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14. ABSTRACT
The goal of the research is to determine if the forces and moments measured by a tri-axial transducer mounted on the pylon of a transtibial prosthesis distal to the socket can be used to estimate the intra-socket pressures and evaluate the effects of different activities, components, and alignments on the residual limb. To date, the instrumentation has been obtained and set up, a systematic review of the literature has been undertaken, the experiments have been designed, a methodology for measuring an alignment has been developed, and IRB approval has been obtained.

15. SUBJECT TERMS
Amputees, prosthesis alignment, socket pressure, gait, force and moment sensors

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Table of Contents

INTRODUCTION

It is proposed that a tri-axial transducer located distal to the socket of a prosthesis will provide valid data that can substitute for more elaborate force-platform and motion capture data, and be used to estimate residual limb impacts due to alignment perturbations, variation in prosthetic component mechanical design, and variation due to type of activity. Transtibial prostheses will be instrumented with a tri-axial transducer and relationships will be modeled using linear transforms and statistical analyses. Relationships between measured forces and moments and perceptions of pressure sensation will be modeled using the Theory of Signal Detection.

BODY

TASK 1

Task 1. To instrument a transtibial prosthesis with a tri-axial transducer to measure the forces and moments transmitted to the distal end of a a socket and synchronize the data with data obtained from a force platform and motion capture system.

An order for a tri-axial transducer, model OTESTSENSOR 45E15A4 with digital output, was ordered from JR3, Inc on 10 September 2007 and received on 21 December 2007. A data processing board and related electronic instrumentation also was ordered on 13 September 2007. The top and bottom of the transducer were machined by JR3 to have four bolt holes in the standard pattern used in prosthetics so that standard prosthetic adaptors could be attached. During the initial setup, a voltage mismatch between the transducer and data processing board resulted in the data processing board being destroyed. JR3 was requested to supply a component having lower voltage, and a new data processing board was purchased.

The heart of the force sensing system is a tri-axial transducer, model 1000N125 from JR3, Inc. The data recording components for the JR3 tri-axial transducer require portability and wireless operation so that it can be carried by a research subject in a variety of environments outside of the laboratory. To satisfy the required conditions, the research team developed the force sensing system by using a PC104/Plus bus-based compact system with a battery power pack and Wi-Fi wireless network access. Figure 1 shows the block diagram of the force sensor system. A PC104/Plus bus based 32bit AMD single board computer comprises the master computer, and the embedded operating system features Windows XP Embedded. The force sensor is connected to the single board computer and DSP processing interface board via a high speed interface cable. The force sensor system is remotely controlled from the operator computer using a Wi-Fi wireless network featuring up to 50Mbytes speed. Table 1 describes the specifications of the force sensor system. The figure 2 is a picture of the force sensor system.

The force sensor system software has been developed using Microsoft Windows XP Embedded which allows a compact size Windows XP operating system to be installed on the single board computer. The operating system enables flexible component selection from thousands of existing Windows applications and drives. Figure 3 shows the Windows dialog developed for displaying instananeous forces and moments at the operator computer interface. The program reads the force and moment data from the force

sensor and saves it to a data file on the single board computer every 10 msec. A test that the system was functioning correctly was made by applying force manually to the transducer and observing the data reported in the display. Subsequent testing will occur during synchronization of the force sensor with the Tekscan F-Socket, forceplate, and Vicon motion capture instrumentation prior to data collection from subjects.

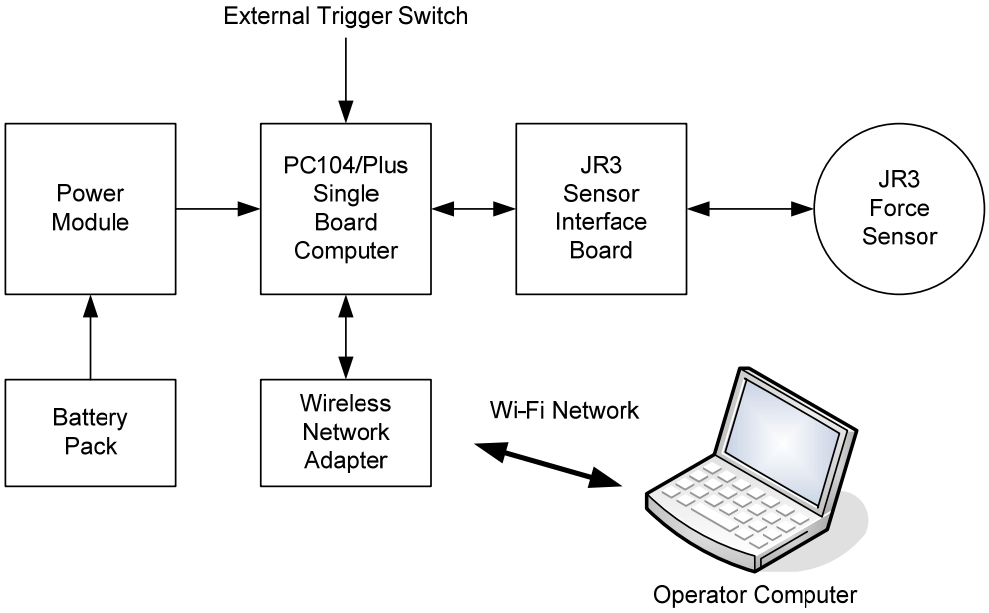


Figure 1. *Force Sensor System Block Diagram*

Table 1. *Force Sensor System Specification*

Item	Specification
Size	8.25 x 5 x 3 inch
Power Battery	14.8V 4400mAh
Computer	Industrial PC/104 Single Board Computer
SBC Operating System	Windows XP Embedded
Wi-Fi Network	Wireless-G with Speed Booster
Operator Computer	Windows XP with Remote Desktop Connection
Force Sensor	JR3 1000N125
Operating Time	above 60 min after complete charge
Minimum Sampling Time	10msec

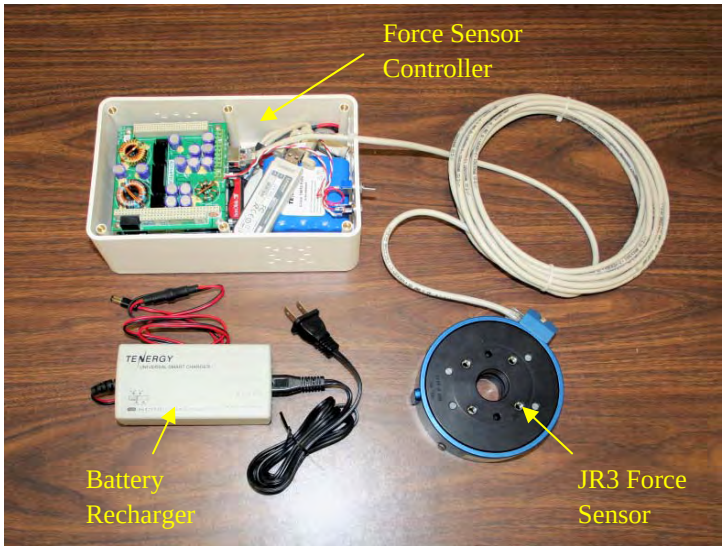


Figure 2. *Picture of Force Sensor System*

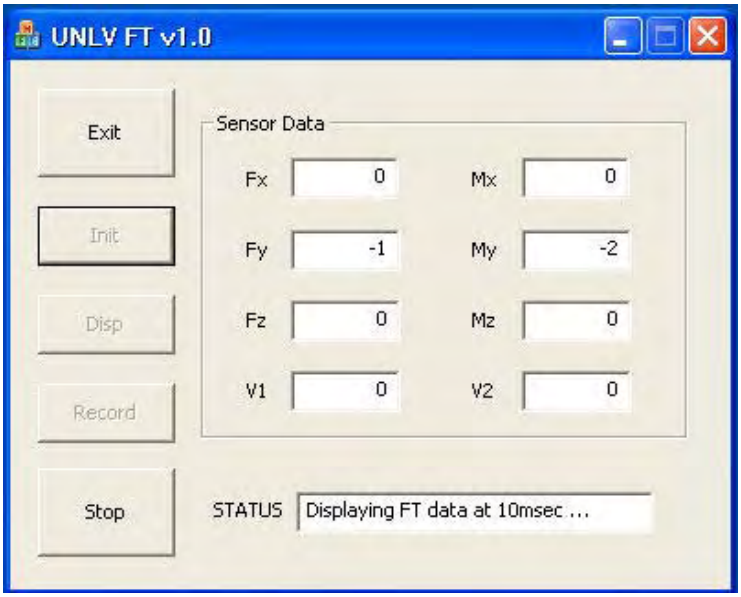


Figure 3. *Dialog Box of Windows Program*

TASK 2

Task 2. To design and conduct experiments, using amputees as subjects, to validate the data obtained from the tri-axial transducer by

a.) comparing transducer data to estimates of forces and moments obtained from force platform and motion capture data during gait

b.) comparing transducer data to estimates of the forces and moments produced by alignment perturbations during gait.

The experiments were designed and data collection forms, a Call for Subjects, and Letters of Informed Consent were prepared. All of these documents are presented in appendix A. The research protocol was submitted to the Army for an IRB pre-review on 25 September 2007 and a response was received from AMDEX on 13 November 2007 with suggested changes. The protocol was modified based on these suggestions and submitted to the IRB at UNLV on 20 November 2007. It was approved by UNLV on 22 April 2008. The protocol was then submitted to USAMRMC and was approved on 8 May 2008. While the experiments have been designed, data collection has not yet begun. It will begin when a Graduate Research Assistant has been recruited and subjects have been obtained. Following are details of the research hypotheses and experimental design.

The research poses six hypotheses which are to be examined using data collected from a convenience sample of three to five amputee subjects in three separate laboratory sessions per subject. The six hypotheses are the following:

1. "As an activity is undertaken by an amputee wearing a properly aligned and fitted prosthesis, variations in the tri-axial forces and moments measured just distal to the base of the socket can be predicted as a linear transformation of variations in measured ground reaction forces and moments". The objective is to determine if tri-axial measurements are consistent with estimates of forces and moments derived using motion capture, force-plate measurements, and inverse dynamics – the method used to estimate joint forces and moments in a gait lab.
2. "If activity and component type are held constant as prosthesis alignment perturbations are made, change in the magnitudes of the forces and moments just distal to the base of the socket can be predicted as linear transformations of the alignment changes". The objective is to determine if tri-axial measurements could be used in a clinical setting to assist with prosthesis alignment.
3. "If component type and alignment are held constant and type of activity is varied, there will be variations in the magnitudes and time-wise patterns of the forces and moments measured just distal to the base of the socket". The objective is to determine if tri-axial measurements can be used to identify the demands placed on the residual limb for activities which cannot easily be measured in a gait lab.
4. "If activity is held constant and alignment is optimal, as the mechanical characteristics of prosthetic components distal to the socket are varied, there will be differences in the time-wise patterns of forces and moments measured at the distal end of the socket. However, the differences may be significant for some activities, but not others, and for some components, but not others". The objective is to determine if tri-axial measurements can detect differences among components having different designs, such as feet, with respect to the forces and moments transmitted to the residual limb.

5. “Variations in pressure measured at the socket-limb interface can be predicted as a transformation function of variations in the forces and moments measured just distal to the socket. The coefficients of the transformation will remain constant during gait, but will vary across activities”. The objective is to verify the findings of a previous study, (46) by using tri-axial transducer measurements and a pressure sensor that has been inserted next to the wall of the socket. If the findings of the previous study can be reproduced, it may facilitate improved methodology for research on residual limbs, sockets, and socket suspension systems.
6. “By applying Signal Detection Theory (TSD), perception of changes in pressure at the socket-limb interface can be modeled as a function of the magnitude of the variations in forces and moments measured just distal to the end of the socket, the coefficients of the transformation identified in hypothesis 5, and the ability of the individual to discriminate pressure differences”. The objective is to determine if models that predict intra-socket pressures as a function of pylon forces and moments (hypothesis 5) can be extended to estimate perceptions of pressure magnitude.

HYPOTHESES

Hypothesis 1

Hypothesis 1 seeks to evaluate the similarity between predictions of transducer measurements of forces and moments based on inverse dynamic modeling and the actual measurements. Reasons for a lack of similarity could be due to energy storage and release characteristics of the prosthetic foot not accounted for by inverse dynamics models, or measurement errors associated with optical motion capture methods based on reflective markers. Since the socket, rather than the foot, is in direct contact with the residual limb, forces and moments at the base of the socket may be better predictors of pressures experienced inside the socket than estimates of socket moments and forces based on inverse dynamic models that are applied to measured ground reaction forces.

Hypothesis 2

Hypothesis 2 tests whether measurable characteristics of gait related to ground reaction force will vary as alignment varies (Hypothesis 2). A systematic State-of-the-Science review of published research articles on transtibial alignment was undertaken in parallel with Task 1 of “Measurement of Forces and Moments Transmitted to the Residual Limb” (60). It followed guidelines established by the American Academy of Orthotists and Prosthetists (56). Data bases searched for articles included RECAL and RECAL Legacy (University of Strathclyde), MEDLINE, Web-O-Knowledge, CINHAL, the Cochrane Reviews, and Science Direct. An initial search uncovered 278 articles which were subsequently narrowed down to 34 articles. Each article was examined carefully to rate the internal and external validity of the study using the criteria presented in the following tables.

Table 1. Internal and External Validity Threats
(Source: State-of-the-Science Evidence Report Guidelines, American Academy of Orthotists and Prosthetists)

Internal Validity Threat Criteria

IV-1 Comparison or control group used – NOT APPLICABLE
IV-2 Groups formed by random assignment – NOT APPLICABLE
IV-3 Groups comparable at baseline – NOT APPLICABLE
IV-4 Groups handled the same way – NOT APPLICABLE
IV-5 Control/comparison group appropriate – NOT APPLICABLE
IV-6 Intervention(s) not blinded
a.) blinding not mentioned or not described
b.) not blinded to subjects involved in determining acceptability of alignment
c.) not blinded to practitioner involved in subjective assessment of alignment or gait
d.) other
IV-7 Inclusion criteria not appropriate
a.) inclusion criteria not mentioned or not described
b.) pooled subject etiology too broad (e.g., bilaterals included with unilaterals)
c.) pooled subject age range includes individuals with dissimilar gait (e.g., pediatric or geriatric mixed with adult)
d.) other
IV-8 Exclusion criteria not appropriate
a.) exclusion criteria not mentioned or described
b.) socket fit not mentioned or described
c.) socket fit loose
d.) associated pathologies present which influence gait (e.g. stroke, recent surgery, open sores)
e.) other
IV-9 Protocol does not address fatigue and learning
a.) potential fatigue and learning influences not mentioned or described
b.) learning likely to occur during experiment and not controlled
c.) fatigue likely to occur during experiment and not controlled
d.) randomization of alignment perturbations appropriate but not reported
e.) other
IV-10 Protocol does not address accommodation and washout
a.) adaptation period not mentioned or described
b.) adaptation period present, but it is 5 minutes or less
c.) no adaptation period
d.) other
IV-11 Attrition reported
a.) reasons for attrition not given
b.) attrition greater than 20%
c.) other
IV-12 Attrition occurs between groups
a.) attrition not equal among groups
b.) other
IV-13 Outcome measures lack reliability
a.) experiments cannot be replicated due to a lack of quantification with respect to
1.) prosthetist's "optimal" or initial alignments
2.) perturbations of alignments
3.) prosthetist's judgment of the acceptability of an alignment
4.) subject's judgment of the acceptability of an alignment
b.) the instrumentation or measurements utilized require subjective interpretation
c.) the instrumentation utilized lacks mechanical or electronic reliability
d.) the precision of the instrumentation is low
e.) other
IV-14 Statistical design and analysis not appropriate
a.) sample size, number of trials, or number of observations is insufficient to compute descriptive statistics (e.g., means

and standard deviations)

b.) sample size, number of trials, or number of observations is sufficient to compute descriptive statistics, but they are not computed

IV-16 c.) tests of significance could be undertaken, but they are not

d.) inappropriate tests of significance are used

IV-17 e.) statistical power is inadequate

f.) other

IV-15 Effect size is not reported

IV-18 Potential conflicts of interest exist

IV-19 Editorial errors exist

a.) contradictions occur within the write-up

b.) statements crucial to understanding the design or results lack clarity

c.) other

External Validity Threat Criteria

EV-1 Sample characteristics are not adequately described

a.) individual variability among subjects in sample pool not reported

b.) other

EV-2 Sample is not representative of the target (clinical) population

a.) only experienced amputees are included

b.) foot technology is limited to older designs (e.g., SACH, single axis, Greissinger)

c.) socket technology is limited to older designs (e.g., PTB with Pelite liner)

d.) other

EV-3 Outcome measures are not adequately described

a) lack of quantification of subjective "acceptability" of alignment by subject or prosthetist a concern

b.) lack of descriptive statistics to facilitate inter-study comparisons a concern

c.) statistical significance not reported

d.) relevant data were collected but not reported

e.) other

EV-4 Outcome measures are not valid for this study

a.) lack of blinding or randomization a concern

b.) subject fatigue or learning a concern

c.) sources of error or bias exist which are a concern (e.g., loose socket fit)

d.) other

EV-5 Intervention not adequately described

a.) lack of quantification of initial or "optimum" or "acceptable" alignments

b.) lack of quantification of perturbations

c.) other

EV-6 Findings clinical significance/relevance threatened by

a.) lack of discussion

b.) lack of recommendations as to acceptable alignment

c.) measurement methods requiring the use of instrumentation that involves

1.) minor investment (e.g. stop watch or simple jigs)

2.) moderate investment (e.g., complex jig, moderately expensive electronics)

3.) major investment (e.g., expensive electronic/microprocessor devices)

d.) need to develop/apply complex mathematical or statistical models

e.) results appear subject specific – there is major unexplained between-individual variation in outcomes reported that may make it hard to apply results to an individual patient

f.) there is major unexplained within-individual variation in outcomes (e.g. trial to trial) reported that make it difficult to determine the effects of the intervention

g.) other

EV-7 Conclusions in context of existing literature

a.) not reported or discussed

b.) appear to contradict other studies

c.) other

EV-8 Conclusions with respect to findings

a.) appear to be biased (e.g., report positive results but not negative results)

b.) appear to overstate or exaggerate findings
c.) contradict data in tables and figures or discussions elsewhere in the study
d.) other

Criteria for Level of Confidence in Findings from Individual Studies

High	The reader has high confidence in the findings of this study. The article is methodologically strong or has methodological issues that are unlikely to impact the confidence with which the outcome statement can be made. Tests of statistical significance have been undertaken.
Moderate	The reader has moderate confidence in the findings from this investigation. There are some methodological issues that detract from our confidence in the findings of the investigation. In cases where a paper is of very high quality but the subject number is very small, our confidence that the outcome is meaningful is reduced.
Low	The reader has low confidence in the findings from this investigation. There are significant methodological issues that compromise the confidence with which outcome statements can be made (i.e., tests of statistical significance were not undertaken). The subject number may be small, but the strength and consistency of the finding within an investigation is also limited.
Insufficient	The outcome parameter is insufficiently or poorly reported or the methodological issues are so significant that the finding needs to be disregarded.

Evidence Statements were prepared, and a level of confidence was assigned to each of them based on the quality of the total evidence. Key criteria were the number of subjects employed in the studies and whether tests of statistical significance were conducted. Additional internal and external validity concerns also were considered. "Level of Confidence" categories for the Evidence Statements are shown in Table 2, below.

Table 2. Level of Confidence in Findings from Multiple Studies as Applied to Evidence Statements

High	The reader has high confidence in the statement based on findings from multiple independent investigations that consistently support the statement. The articles, on the whole, are methodologically strong; or where methodological issues occur, they are unlikely to impact the confidence with which the statement can be made.
Moderate	The reader has moderate confidence in the statement based on at least two independent investigations, or one study having a high level of confidence that is supported by biomechanics theory and principles. There may be investigations of very high quality, but small subject numbers reduce the confidence with which statements can be made.
Low	The reader has low confidence in the statement. There are significant methodological issues that compromise confidence with which the statement can be made (i.e. lack of tests of statistical significance). In cases where a single, methodologically strong paper is found to support this statement, but biomechanics theory and principles tend to refute it, the confidence with which the statement can be made is considered low in the absence of independent corroborative evidence.
Insufficient	The reader has no confidence in the statement due to several investigations reporting conflicting results, or a lack of tests of statistical significance and independent corroborative evidence. There may be significant methodological issues that compromise the confidence with which the statement can be made, particularly if the statement is based on a single poor quality investigation, very small subject numbers, or where the results from a single study contradict biomechanics theory and principles.

The major findings of the Review were that for the controlled environments in which the studies were carried out (e.g. gait lab or clinic), among experienced unilateral transtibial amputees walking for short periods of time on a level surface during experiments in which alignment was being examined,

1. A range of acceptable alignments appears to be acceptable to the amputee, and the range varies from individual to individual (3, 8, 14, 26, 42, 51)-*High Confidence;*
2. No significant differences in walking velocity occur with perturbation of socket angular

alignment, foot position, or foot external-internal rotation with respect to an acceptable alignment (3, 7, 8, 10, 35, 37, 45)- *High Confidence;*
3. No significant differences in cadence occur with perturbation of socket angular alignment, foot position, or foot external-internal rotation with respect to an acceptable alignment (3, 7, 35, 45)-*Moderate Confidence;* and
4. Many kinematic and kinetic variables are significantly different between the prosthetic limb and contralateral limb with an acceptable alignment (1,3, 8, 11, 12, 21,24, 38, 45). *Moderate Confidence*

A small amount of evidence (usually rated as "Insufficient") indicated that many of the forces and moments measured in the pylon or by a forceplate may not show statistically significant differences for perturbations about an alignment that is acceptable to the amputee. The perturbations examined and findings of the Evidence Report are summarized below. If a statement is labeled as "Insufficient Evidence", the wording of it reflects what was suggested by the limited evidence.

Socket Flexion and Extension (tipping the socket anterior and posterior with respect to an acceptable alignment, respectively)
1. No significant differences in peak vertical ground reaction force on the prosthetic limb will occur (11, 24, 31, 33, 36, 45)-*Insufficient Evidence;*
2. Significant effects on the times of occurrence of peak ground reaction forces on the prosthetic limb will occur (31, 33, 35)-*Insufficient Evidence;*
3. Significant effects on the patterns and durations of ground reaction forces on the prosthetic limb will occur (7, 25)-*Insufficient Evidence;* and
4. No significant differences in ground reaction force impulses on the prosthetic limb will occur (24). *Insufficient Evidence*

Socket Abduction and Adduction (tipping the socket toward and away from and the medial side with respect to an acceptable alignment, respectively)
1. No significant differences in peak vertical ground reaction force on the prosthetic limb will occur (11, 24, 45)- *Moderate Confidence;*
2. Significant effects on peak medial-lateral ground reaction forces on the prosthetic limb will occur (45)-*Moderate Confidence;*
3. No significant effects on the times of occurrence of peak ground reaction forces on the prosthetic limb will occur (35)-*Insufficient Evidence;* and
4. No significant effects on vertical ground reaction force impulse on the prosthetic limb will occur (24)-*Insufficient Evidence.*

Anterior-Posterior Translation of the Foot Relative to the Socket (with respect to an acceptable alignment)
1. Significant effects on the times of occurrence of peak ground reaction forces on the prosthetic limb will occur (35)-*Insufficient Evidence;* and
2. Significant effects on the patterns and durations of the ground reaction forces on the prosthetic limb will occur (7)-*Insufficient Evidence.*

Medial-Lateral Translation of the Foot Relative to the Socket (with respect to an acceptable alignment)
1. Significant effects on the times of occurrence of peak ground reaction forces on the prosthetic limb will occur (35)-*Insufficient Evidence.*

Internal-External Rotation of the Foot Relative to the Socket (with respect to an acceptable alignment)
1. No significant difference in peak ground reaction force on the prosthetic limb will occur (3, 45)-*Moderate Confidence.*

Plantar Flexion – Dorsi Flexion of the Foot Relative to the Socket (with respect to an acceptable alignment)
1. Anterior-posterior ground reaction force oscillations reflecting knee instability at the transition from a posterior to anterior direction will occur earlier for foot plantar flexion and later for foot dorsiflexion and will exhibit greater magnitudes (38)-*Insufficient Evidence.*

The studies conducted to date suggested that the magnitudes of the pylon axial peak forces measured by the transducer, which correspond to peak vertical ground reaction forces, may not show significant differences with alignment perturbations. Forces perpendicular to these, which correspond to medial-lateral and anterior-posterior ground reaction forces, may or may not show significant differences. Timings of peak forces and force patterns may or may not show significant differences. The small amount and low quality of evidence from these studies made it difficult to place confidence in any hypotheses related to horizontal ground reaction forces. One of the benefits from the study of "Measurement of Forces and Moments Transmitted to the Residual Limb" will be to add to the evidence base, which may enable some of the Evidence Statements to move from the category of "Insufficient Evidence" to a higher level of confidence.

The articles reviewed also implied that measurements of the forces and moments in the pylon may not offer an objective means for identifying an acceptable or optimal alignment. To be able to identify an optimal alignment, one or more measurable parameters of gait kinetics or kinematics must show a minimum or maximum at the preferred alignment. Only two studies revealed departures from minimum or maximum values of ground reaction force variables to occur as an acceptable alignment was perturbed, and the quality of the evidence was insufficient to assign any confidence to the findings (21, 38). These studies reported that plantar flexion and dorsi flexion of the foot with respect to an acceptable alignment produced oscillations in the anterior-posterior ground reaction force during the interval when the force transitions from a braking direction to a propulsive direction. The authors hypothesized that as an alignment departed from an optimum, the less smooth the transition would be, reflecting instability. However, an objective means for measuring these oscillations so that tests of statistical significance could be conducted was not presented, and the number of subjects included in the studies were small – two and one, respectively. If the magnitudes of these oscillations increase with perturbation of an optimal alignment as hypothesized by the studies, this should be detectable with a transducer mounted in the pylon.

Other studies suggested that joint kinematic, kinetic and muscle activity variables (for the knee, in particular) might have minimum or maximum values at an acceptable alignment (1, 3, 7, 8, 9, 12, 37, 45, 47). Most of these studies resulted in findings of Insufficient Evidence, but when considered together, imply that the search for an "optimal" alignment may need to focus on measurements taken at the joints or EMG measurement of muscle activity instead of forces at the ground or in the pylon. The transducer, if the sole source of measurements, will not facilitate examining any hypotheses related to joints or muscle activity.

A limited number of studies of leg muscle EMG activity and total body oxygen uptake presented the following evidence:

1. Oxygen uptake increases with foot plantar or dorsiflexion or foot anterior-posterior translation (37)-*Insufficient Evidence*;
2. Total body joint work or energy is at a minimum for acceptable socket flexion-extension angular alignment (47)-*Insufficient Evidence*;
3. The vastus lateralis muscle on the prosthetic limb exhibits increased EMG activity when the prosthetic foot is translated in a posterior direction but not when the foot is translated in an anterior direction with respect to an acceptable alignment (7)-*Insufficient Evidence*;
4. The vastus lateralis musle on the prosthetic limb shows increased EMG activity when the socket is flexed or extended with respect to an acceptable alignment (7).-*Insufficient Evidence*;
5. Gluteus medius and biceps femoris long head activity on the prosthetic limb are prolonged by medial translation of the foot and reduced by lateral translation of the foot (7)-*Insufficient Evidence*; and
6. The gluteus medius and biceps femoris long head muscles on the prosthetic limb exhibit longer EMG activity when the socket is abducted, and shorter EMG activity when the socket is adducted (7)-*Insufficient Evidence*.

Studies of joint kinematics and kinetics reported the following evidence for bilateral knee joint symmetry:

Bilateral peak knee joint flexion relationships (symmetries) are significantly affected when an acceptable alignment is perturbed with respect to socket angular alignment or foot position (1, 8, 12)- *Insufficient Evidence.*

The studies reviewed reported the following evidence for joints on the prosthetic and contralateral limbs:

1. Peak external knee joint moments are significantly affected by socket flexion and extension (7, 9, 45)-*Insufficient Evidence*;
2. Peak external knee joint moments in the frontal plane increase significantly with socket abduction and adduction with respect to an acceptable alignment (7, 45)-*Insufficient Evidence*;
3. Peak hip flexion angle during stance, peak knee flexion angle during stance, and peak knee flexion angle during swing decrease significantly with anterior translation of the foot (1)-*Insufficient Evidence*;
4. Peak knee flexion moment increases when the foot is shifted posterior and the tendency toward a knee extension moment increases when the foot is shifted anterior (37)- *Insufficient Evidence*;

5. External hip and knee adduction moments increase with medial translation of the foot and decrease with lateral translation of the foot (7)-*Insufficient Evidence*;
6. Foot dorsiflexion prolongs the knee flexion moment and decreases its magnitude, and foot plantarflexion decreases the peak knee flexion moment more rapidly and increases the peak knee extension moment (37, 45)-*Insufficient Evidence*;
7. Peak knee flexion angle on the prosthetic limb decreases significantly with internal rotation of the prosthetic foot by 6° from an acceptable alignment and increases on the contralateral limb (3)-*Moderate Confidence*; and
8. Peak external knee extension moment, impulse, and work on the contralateral limb increases significantly with 6° of internal rotation of the foot, but there are no significant increases in these variables with 6° of external rotation (3)-*Moderate Confidence*.

Theory concerning the role of the roll-over shape of the foot in producing an acceptable alignment further supports the notion that joint kinematic and kinetic variables may be better indicators of optimal alignment than ground reaction force and pylon force variables. Studies have produced evidence at a high level of confidence that a range of alignments are acceptable to the amputee (3, 8, 14, 20, 26, 42, 51). This appears to be explainable by the roll-over shape characteristics of the prosthetic foot. Evidence at a moderate level of confidence supports the notion that during alignment, the prosthetist matches the sagittal plane roll-over shape of the prosthetic foot to the contra lateral limb anatomic foot (14). Virtual leg length represents the functional radius of the leg and determines the vertical excursion of the pelvis during stance (61). Virtual leg length is determined by the anatomic length of the lower limb, and a roll-factor at the foot. The roll-factor of the foot is a function of roll-over shape and alignment of the foot. To produce an energy efficient gait, the virtual leg lengths of both limbs should be identical. Otherwise, the vertical excursion of the pelvis will not be symmetrical. Equal virtual leg lengths are achieved by matching the roll-over shape of the prosthetic foot to the anatomic foot through alignment. Virtual leg length defines the radius of an arc, and it is possible to maintain the roll-over shape of the foot along this arc by combinations of angular adjustment and anterior-posterior translation over a small range. As long as alignment achieves a foot position along a portion of this arc, the alignment may be acceptable. It stands to reason that if an alignment does not position the prosthetic foot along this arc, virtual leg length on the prosthetic limb will be either longer or shorter than virtual leg length on the contra-lateral limb, and the compensatory behavior necessary to achieve similar virtual leg lengths may necessitate alterations in joint kinematics and kinetics, particularly at the knee. The paradigm of virtual leg length, foot roll-over shape, and knee kinematics may help explain the conditions for an optimal alignment. Unfortunately, these hypotheses cannot be examined with the tri-axial transducer.

Hypothesis 3

Hypothesis 3 will examine the effects that type of activity may have on the forces and moments measured at the transducer. Activities that will be examined include walking at a speed 10% to 15% faster than a self-selected comfortable walking speed, ascending and descending approximately 10 to 15 steps, walking up and down a ramp with a 5% slope, walking across a slope of 2% to 5%, and walking in a circle with a diameter of 10 feet. The State-of-the-Science Review found one study that examined the effect of slope on the range of alignment settings acceptable to the individual (42). The study provided evidence at a moderate level of confidence that the range of perturbations amputees will accept decreases when walking takes place on inclined surfaces. Published research articles on the activities to be examined in

"Measurements of Forces and Moments Transmitted to the Residual Limb" for transtibial amputees are small in number and include articles on walking with variable cadence (62, 63), climbing stairs (64, 65, 66), and walking on inclines (42, 67).

Hypothesis 4

Hypothesis 4 will examine the effect that different types of prosthetic feet may have on the forces and moments measured at the transducer. Besides the foot the amputee subjects currently are wearing, solid-ankle cushion-heel (SACH) feet will be examined to determine if transducer measurements show significant differences between the SACH foot and the current foot. A review of those research studies that have examined the effect of energy storage and return (ESAR) prosthetic feet reported that no statistically significant effects have been found for walking speed, cadence, or stride length, though trends are present in the data (68**)**. Studies of temporal characteristics revealed effects on the heel-only and mid-stance support times, but the authors of the review concluded that evidence was minimal to refute or accept this, and the results may be due to foot alignment. No statistically significant effects were found for the first and second peak vertical ground reaction forces on the prosthetic limb. Only trends lacking statistical significance have been reported for the contra-lateral limb. Similarly, no statistically significant effects have been found for braking force on the prosthetic limb. Propulsive force appeared to increase on the prosthetic limb with ESAR feet, but evidence was too limited to draw conclusions with any confidence. Insufficient evidence was available to determine if ground reaction force impulse is affected on the prosthetic limb. Statistically significant effects were not found for external peak hip moment. Peak knee moment effects have been inconclusive, with some reporting that SACH feet produced a dominant external flexor moment during loading response whereas some ESAR feet produced an extensor moment, though this may have been due to alignment. Differences in peak external ankle moment appeared to be a function of ESAR foot design, however these calculations were based on the assumption that an ankle joint with a fixed center of rotation existed. Increased ankle ROM was reported with ESAR feet, which was probably due to the flexible keel, which delayed heel rise in late stance. This appeared to contribute to a longer contra-lateral limb step length and decreased contra-lateral limb peak vertical ground reaction force at heel strike. The lower contra-lateral limb peak ground reaction force may have been due to a lower center-of-gravity during the sound side step, made possible by the deflection of the ESAR keel. A limited number of EMG studies of the lower limb muscles have been carried out, and all consistently reported no significant differences in the intensity or duration of activity. Studies reported statistically significant but marginal effects of ESAR feet on metabolic cost, with the effect becoming more pronounced as walking speed increased beyond a self-selected comfortable speed.

Because the transducer measures effects at the socket rather than the ground, the transducer may improve understanding of the benefits of ESAR feet. Effects on peak vertical pylon forces may not be significant. Anterior-posterior forces and impulse effects may or may not be significantly different. The transducer does not require the assumption that the ankle joint has a fixed center of rotation which enables it to measure the effect of the foot type on the socket and residual limb. Ankle joint moments, which are expected to differ between ESAR and SACH feet, may or may not have an effect at the socket that can be detected in the moments recorded by the transducer. If muscle activity on the prosthetic limb does not change, then moments recorded by the transducer may show differences, since the moments at the base of the socket must have a value that lies between those at the knee and those at the ankle, and the moments at the knee would be expected not to change as long as muscle activity remained constant. However,

moments at the ankle would change as a function of foot type. If muscle activity on the prosthetic limb does change, then moment differences at the base of the socket may not be detected. If there are no differences in moments at the base of the socket, then it may imply that muscle activity of the lower limb is changing to compensate for changes in the biomechanical performance of the ankle. Unfortunately, transducer measurements will not provide direct evidence of what is occurring at either the ankle, the knee joint, or with the muscles that control the knee joint. Nor will the transducer provide evidence on metabolic cost.

In addition, one major limitation of the transducer is that it cannot be installed on a prosthesis with a J-shaped ESAR foot (e.g., Flex-Foot) because it would require shortening the vertical strut of the foot. Upon removal, the strut would be short and would require at least 2 inches of extension to mate correctly with the socket. This could influence the performance of the foot since a portion of the ESAR section would be lost. With a J-shaped foot, it would work only if a foot with a shortened strut were used, which suggests use of a temporary foot for data collection and a different foot with the full strut for actual use.

Hypothesis 5

Hypothesis 5 seeks to examine the relationship between the forces and moments in the pylon and those exerted on the residual limb inside the socket. As mentioned above, a previous study was able to estimate the pressures inside a transtibial socket using measurements of the forces and moments in the pylon (46). As part of the study, alignment of the prosthesis was varied, and the sensitivity of pressures to changes in alignment were modeled as a function of the alignment changes. The models used were

$$\begin{vmatrix} \sigma_p(\theta,t) \\ \sigma_g(\theta,t) \end{vmatrix} = |W(\theta)| * \begin{vmatrix} F_z(\theta,t) \\ M_x(\theta,t) \end{vmatrix}$$

Where:

$\sigma_p(\theta,t)$= pressure on the patellar tendon region

$\sigma_g(\theta,t)$ = pressure on the gastrocnemius region

$W(\theta)$ = matrix of coefficients that relate pylon forces and moments to socket pressures

$F_z(\theta,t)$ = axial force in the pylon

$M_x(\theta,t)$ = flexion-extension moment in the pylon

θ = socket flexion-extension perturbation with respect to an acceptable alignment

t = time during the gait cycle

And

$$|W(\theta)| = \begin{vmatrix} W_{11} + \left(\frac{dW_{11}}{d\theta}\right) * \theta & W_{12} + \left(\frac{dW_{12}}{d\theta}\right) * \theta \\ W_{21} + \left(\frac{dW_{21}}{d\theta}\right) * \theta & W_{22} + \left(\frac{dW_{22}}{d\theta}\right) * \theta \end{vmatrix}$$

The model added the pressure effects created by pylon axial forces to the pressure effects created by pylon flexion-extension moments. It was calibrated using regression analysis by entering pressure as the dependent variable and force and moment and socket alignment perturbation as the independent variables. Observations consisted of variable values sampled at uniform intervals during the gait cycle over multiple

steps. The authors reported correlation R values of 0.937 in the patellar region and 0.984 in the gastrocnemius region for the first subject in the study, and values of 0.938 and 0.989 respectively for a second subject. The forces and moments represented in the above model will be measured by the tri-axial transducer instrumentation as described under Task 1 when it is mounted distal to the socket and a subject walks. The model can be extended to multiple sites inside the socket and pylon forces and moments in three dimensions, and will be used to examine Hypothesis 5.

In the study cited above and previous studies of intra-socket pressures, the pressures were measured by instrumentation that required drilling holes in the socket at a limited number of points, usually between 6 and 12, which limited the use of these methods in clinical settings. "Measurement of Forces and Moments Transmitted to the Residual Limb will employ methods that do not compromise the integrity of the socket. The pressures will be measured by Tekscan's F-Socket, which employs a matrix of 96 force-sensing resistors (FSR). The sensor strip is 21.5 X 7.5 cm and approximately 0.28 mm thick, and allows pressures to be measured simultaneously over a number of regions inside a socket.

The study cited above and several others provided evidence at a moderate level of confidence that peak pressure on the residual limb increases at the distal tibia and decreases at the patella tendon as socket alignment changes from acceptable to one of greater flexion, whereas it deceases at the distal tibia and increases at the patella tendon as socket alignment changes from acceptable to one of greater extension (7, 23, 31, 35, 36, 46, 52). Additional evidence statements and the associated levels of confidence developed as a result of the State-of-the-Science review are as follow:

1. The times of occurrence of intra-socket peak pressures are significantly affected when an acceptable socket flexion-extension alignment is perturbed (31, 52)-*Insufficient Evidence*.
2. The times of occurrence of intra-socket peak shear stresses are significantly affected when an acceptable socket flexion-extension alignment is perturbed (31)-*Insufficient Evidence.*
3. The patterns and durations of intra-socket shear stresses are significantly affected when an acceptable socket flexion-extension alignment is perturbed (52)-*Insufficient Evidence.*
4. Pressure on the distal tibia increases with posterior translation of the foot and decreases with anterior translation of the foot with respect to an acceptable alignment (7, 23, 35)-*Moderate Confidence.*
5. Intra-socket peak shear stresses on the residual limb are significantly affected with anterior and posterior translation of the foot with respect to an acceptable alignment (35)-*Insufficient Evidence.*
6. Intra-socket peak pressures on the residual limb are increased significantly on the lateral distal tibia and decreased on the medial distal tibia when the socket is abducted from an acceptable alignment (7, 23, 35)-*Insufficient Evidence*.
7. Intra-socket peak shear stresses are significantly affected when the socket is perturbed by abduction or adduction from an acceptable alignment (35)-*Insufficient Evidence*.
8. Intra-socket pressures at the lateral distal tibia increase when the foot is translated medial and decrease when the foot is translated lateral from an acceptable alignment (7, 23, 35)-*Moderate Confidence*.
9. Intra-socket pressures at the lateral tibial condyle decreae when the foot is translated medial and increase when the foot is translated lateral from an acceptable alignment (23)-*Moderate Confidence.*

10. Intra-socket peak shear stresses are significantly affected when the foot is translated medial or lateral from an acceptable alignment (35)-*Insufficient Evidence.*
11. Heel wedging increases peak pressure at the distal end of the tibia, and forefoot wedging increases pressure in the subpatellar region (41)-*Moderate Confidence*.
12. Heel wedging increases the time to occurrence of peak pressure in the subpatellar region (41)-*Moderate Confidence*.
13. Heel wedging decreases signal power in the subpatellar region and increases signal power at the distal end of the tibia, and forefoot wedging increases signal power in the subpatellar region and decreases signal power in the distal end of the tibia (41)-*Moderate Confidence*.

As originally envisioned in the research proposal and IRB protocol, evidence will be collected on pressure changes resulting from foot translation in the anterior-posterior and medial-lateral directions. This data will provide additional evidence for several statements that currently are rated as having either insufficient evidence or only moderate confidence. Socket angular perturbations or foot angular alignment perturbations (dorsi-flexion and plantar-flexion) were not included in the research plan, although they would be likely to produce changes in intra-socket pressures. It is not known if the magnitudes of the perturbations envisioned in the plan, a maximum of $\pm$ 1.5 cm with respect to acceptable alignment, will produce significant changes.

Hypothesis 6

Hypothesis 6 will explore methods for measuring amputee perceptions of intra-socket pressure changes as a result of small alignment perturbations. The State-of-the-Science review found that no research study to date has undertaken a scientific approach to the measurement of alignment perception. Studies that reported on the range of acceptable alignments appeared to make the assumption that acceptance changes dramatically with a small incremental change in alignment. In the studies, the range of acceptable alignments was presented without discussion of how acceptability was measured (8, 14, 20, 26, 42, 51). The published results implied that researchers viewed acceptability as a zero-one (0 or 1) phenomenon; an alignment was either completely acceptable or completely unacceptable to the amputee. In some cases, the judgment of acceptability was made by the prosthetist. Previous research indicated that pressure changes occur gradually with small perturbations in alignment (23, 46, 52). According to the theory of psychophysics, there should be a gradual change in the perception of pressure magnitude with small changes in pressure. For purposes of research, acceptability should be conceived of as a stochastic variable, with probabilities that vary as alignment changes. With gradual changes in pressure, there also should be changes in the amputee's subjective expectation that the alignment will be unacceptable. With increasing pressure, the probability that an alignment will be perceived as unacceptable should approach 1.0.

The approach to be taken in "Measuring the Forces and Moments Transmitted to the Residual Limb" hypothesizes that perception of pressure and alignment acceptability is probabilistic and can be explained best by the Theory of Signal Detection, which is a theoretically useful way to conceptualize perception and judgment of pressure, pain, and force. The Theory of Signal Detection incorporates three basic variables in a probabilistic model of judgments: 1.) the magnitude of the signal (i.e., pressure); 2.) the ability of the subject to detect differences in signal strength (sensitivity to changes in pressure); and 3.) the relative benefits and costs to the subject of correctly concluding that a signal is absent when it is

absent and correctly perceiving that a signal is present when it is present (how much discomfort will be experienced for the activities of the amputee). Following alignment perturbations in the experimental portion of the project, subjects will be asked to report sensations of pressure changes in various regions of the residual limb and their certainty about the changes. Acceptability also will be measured. This approach will allow signal detection models to be fitted to the data. The signal detection models will facilitate a determination of the probabilistic nature of the boundary between an acceptable and an unacceptable alignment, and the how rapidly perceptions change.

Measurement of Alignment

One of the major findings of the State-of-the-Art review of transtibial alignment was that very few of the studies quantified the acceptable alignments. Typically, the starting point for examining perturbations was an initial acceptable alignment that had been established by a prosthetist. This lack of quantification may have been due to the difficulty of physically measuring a complete alignment involving foot translation and angular orientation, and socket angular orientation. From a strictly scientific viewpoint, this means that the initial starting conditions of these studies cannot be reproduced, which lowers the quality of the evidence. Since amputees appear to find a range of alignments acceptable, results stemming from perturbations may change as the initial acceptable alignment moves along the range of acceptable alignments. Results might be dramatically different for identical perturbations to initial alignments at opposite ends of the range of acceptability.

The few studies that measured the initial alignment involved specially constructed jigs and socket axis alignment devices (2, 8, 26, 30, 42, 43, 51, 58). None of this instrumentation was available for this project, and an original methodology compatible with the needs of the project had to be developed. A major requirement was that the methodology had to avoid the construction of jigs that involved machine shop work since the project budget did not include this. This limited the approach to the use of laser beams and scales for measuring coordinates and angles. The set up is shown below and the methodology is described beginning on the following page. It has not yet been field tested. A key requirement for field use is speed. A subject cannot be expected to wait hours while an alignment is measured.

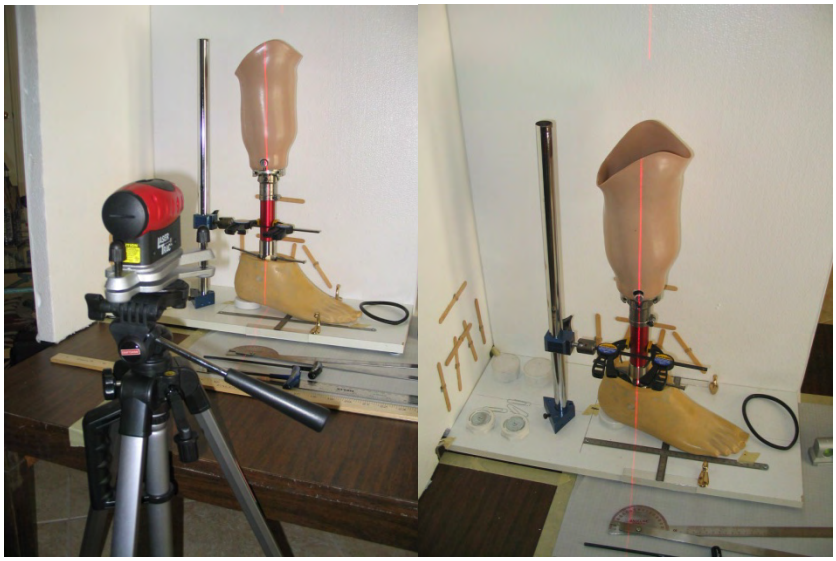


Figure 4. Alignment measurement table showing laser line projected on prosthesis. Graph paper is used to mark and measure coordinates. Appreciation is expressed to Ossur for providing the measurement jig.

ALIGNMENT MEASUREMENT METHODOLOGY

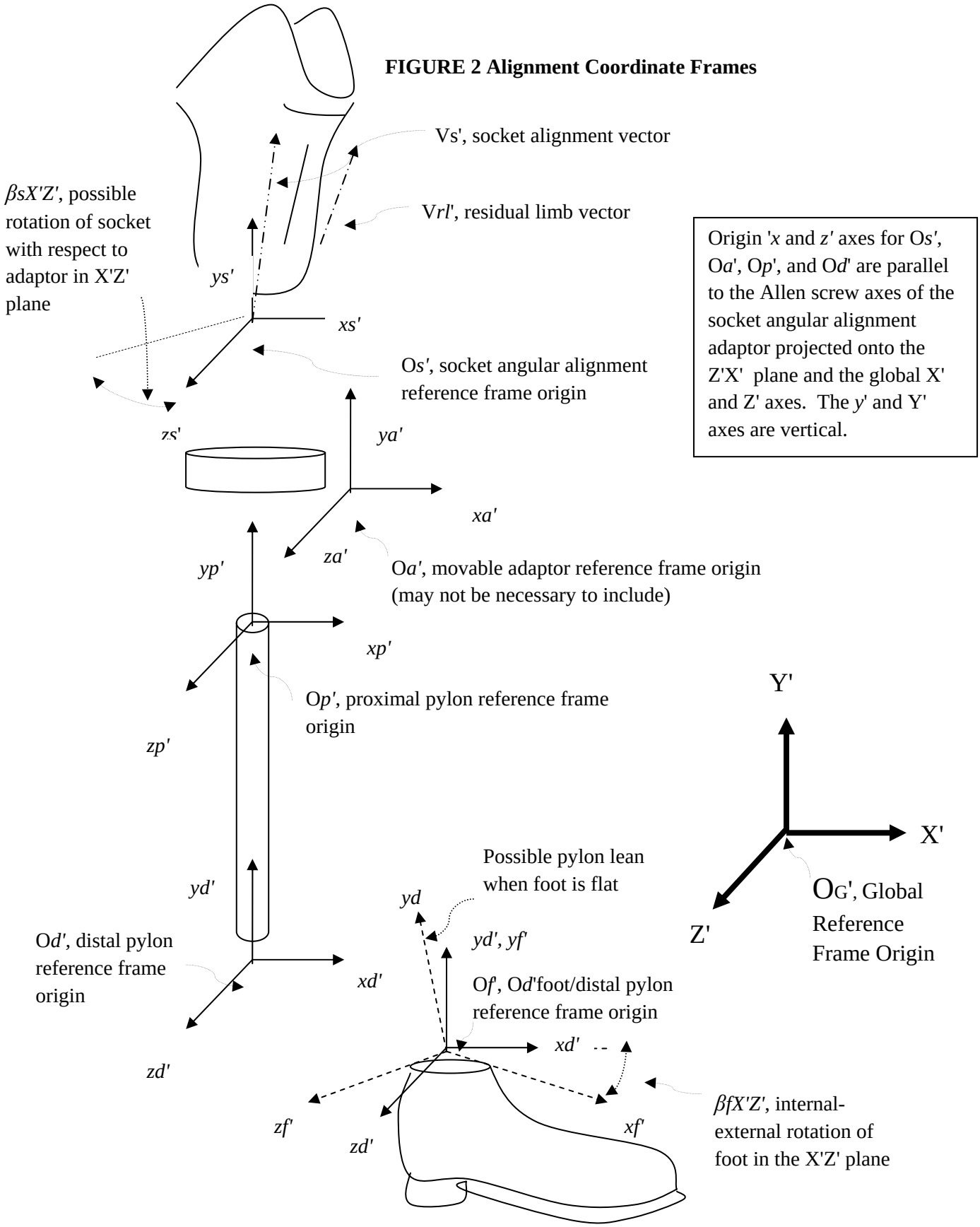
Introduction

The goals are to measure a.) socket angular orientation with respect to a vertical line perpendicular to the bottom of the foot, and b.) foot linear translation with respect to the center of the socket. Inexpensive lasers that produce horizontal and vertical lines are used to obtain the coordinates of key components in three dimensions (X, Y, Z), or projection angles and computations are performed to obtain direction cosines, angles and translations. The measurement system can be used in a space that need be no larger than 3' X 3' X 3'. The methodology emphasizes scientific reproducibility, and attempts to minimize the need to apply subjective judgments. The need for reproducibility addresses two possible scenarios: first, a researcher may need to reproduce an alignment previously measured; and second, different researchers may wish to study prostheses with similar alignments or integrate findings from multiple studies. To accomplish this, the methodology utilizes the Allen screws of modular components, which are oriented at right angles and control the angular orientations of the socket and foot. Measurements are made of the X,Y,Z coordinates of the Allen screws and reference frame origins are placed at the approximate center where the screw axes cross inside the components.

The methodology measures alignment in two steps using two sets of measurements taken separately, and then combines them by means of matrix operations. The first set of measurements are of socket angular orientation and translation with respect to the proximal end of the pylon and are taken in a global coordinate system having axes X', Y' and Z'. In the X' Y'Z' global frame, the pylon axis is oriented vertically and parallel to the global Y' axis. Thus, socket angles are measured with respect to a vertical pylon. The bottom of the foot need not be perpendicular to the pylon and flat on the floor. The X"Y"Z" global frame accounts for foot internal-external rotation. The X'"Y'"Z'" global frame which features the foot flat on the floor and accounts for possible pylon lean. All of these measurements will be noted with primes (', ", '") to indicate successive transformations.

Figure 1 indicates the reference frame origins for the first step. Plane X'Y' represents the sagittal alignment plane of the socket. Axis Y' is parallel to the pylon axis and axis X' is perpendicular to the pylon. Plane X'Y' is aligned parallel to the axes of the Allen screws which control the angular alignment of the socket in the sagittal plane. The Y' axis points vertically, and the X' axis points in the direction of walking. Plane Y'Z' represents the frontal alignment plane of the socket. The Z' axis is perpendicular to the X' and Y' axes, and the plane Y'Z' is parallel to the axes of the Allen screws which control the angular alignment of the socket in the frontal plane. The orientation of the Z' axis follows the right hand rule, and on a right-side prosthesis will point laterally, and on a left-side prosthesis will point medially. The key local reference frames in the X'Y'Z' global system are the foot local reference frame, O*f*', which is the origin for foot angular adjustment; the proximal pylon local reference frame, O*p*'; the distal pylon local reference frame, O*d*', which shares an origin with O*f*'; the socket angular alignment local reference frame, O*s*', which is the origin for socket angular adjustment; and the origin of any movable adaptors that are located between the socket adaptor and the pylon for purposes of linear translation of the foot, O*a*'. In many cases this adaptor, if present, need not have measurements taken of it since its effect on alignment will appear in the location of the socket angular adjustment origin, O*s*' with respect to the proximal pylon

FIGURE 2 Alignment Coordinate Frames



Origin '*x* and *z'* axes for Os', Oa', Op', and Od' are parallel to the Allen screw axes of the socket angular alignment adaptor projected onto the Z'X' plane and the global X' and Z' axes. The *y*' and Y' axes are vertical.

local reference frame, O*p*'. The distal end of the pylon is assigned a reference frame, O*d*', with axes parallel to O*p*'. The local x' and z' axes of all of these local frames of reference except for the foot, O*f*', are oriented parallel to the global axes X' and Z'. Foot angular rotation with respect to the X'Z' plane is measured as angle $\beta fX'Z'$ and used to establish the orientation of the foot/distal pylon reference frame, O*f*', when the pylon is vertical. This angle is assumed to represent the internal-external rotation of the foot with respect to the socket. If the pylon leans slightly when the foot is flat, this method of measuring internal-external rotation of the foot may introduce a slight error into the angle of rotation as experienced during gait when the foot is flat on the floor, but not by a clinically significant amount unless there is an extensive amount of lean in the pylon.

The second set of measurements determines any additional medial-lateral and anterior-posterior translation of the socket and change in angular orientation that occurs when the bottom of the foot is flat on the floor. The global reference frame for these measurements is denoted as X'''Y'''Z'''. This is the global system that ultimately will be used to describe socket angular orientation and translation. A strong elastic strap is used to ensure the foot is flat on the floor and the foot axes O*fx* and O*fz* are positioned to be parallel to the global axes X''' and Z'''. The translation of the proximal pylon origin, O*p*, is measured relative to the foot/distal pylon origin, O*f*. Matrices that combine rotation and translation are then used to compute the socket angular orientation and translation in the global X'''Y'''Z''' frame.

Socket Orientation and Translation Relative to a Vertical Pylon

A. Set Up

1. Set up the graph paper. Align the axes to parallel the edges of the platform on which it rests. The edges constitute the global X' and Z' axes.

2. Attach the pylon to post. The shoe may be donned or doffed.
    a.) Attach the pylon to the bracket; use an appropriate heel block to attain a level top of the foot.
    b.) Insert Allen wrenches in the Allen screws that control the socket M-L or A-P angular alignment
    c.) Align the pylon so that the wrenches parallel the grid X' or Z' axes (eyeball)
    d.) Bring the pylon to vertical (use a level or laser); the axis of the pylon should be parallel to the global Y' axis.

B. Transverse Plane Measurement of Foot Angle, $\beta fX'Z'$

1. Insert Allen wrenches into the Allen screws that control foot plantar and dorsi-flexion.

2. By moving the position of the tripod, align a vertical laser that passes through the center of the Allen screw and bisects the Allen wrench. This line represents $\beta fX'Z'$

3. Mark the position of the extension of this line on the graph paper.

4. Measure the angle from axis X' with a protractor

5. Place a black dot on the anterior end of the foot where the laser line first touches it (this can be used in the second step to confirm foot orientation when foot axes O*fx*, O*fz* should be parallel to X and Z).

C. Transverse Plane Measurement of Possible Socket Rotation with Respect to the Socket Alignment Reference Frame, Os, (Angle *βsX′Z′*)

1. Place a protractor on the back of the socket in a horizontal position just below the posterior shelf with one arm on the global Y'Z' plane. Measure angle β*sX′Z′* from the Y'Z' plane.

D. Frontal Plane Measurements of Foot/Distal Pylon Reference Frame Origin Global Coordinates O*fY′*, O*fZ′* and O*dY*', O*dZ*'.

1. Place a vertical laser line through the center of the distal pylon and mark and measure the O*fZ* ' (O*dZ*') coordinate on the graph paper.

2. Place a horizontal laser line through the center of the ankle Allen screws and use a scale to measure O*fY′* (O*dY*').

E. Frontal Plane Measurement of Proximal Pylon Reference Frame Origin Global Coordinates O*pY′*, O*pZ′*.

These coordinates will be used for measuring foot M-L translation.

1. Assume O*pZ′* = O*fZ′* if pylon is vertical; if in doubt, measure as in D.1 above.

2. Place a horizontal laser line through the center of the Allen screw at the top of pylon or through the proximal end of the pylon tube clamp if there are no Allen screws.

3. Measure the height of the horizontal laser line above the platform with a scale to obtain O*pY′*.

F. Frontal Plane Measurement of Socket Angular Alignment Reference Frame Origin Global Coordinates O*sY′*, O*sZ′*.

Socket angular perturbations in the frontal and sagittal plane have a center of rotation at this origin.

1. Place a vertical laser line through the center of the Allen screw that controls A-P angular alignment of socket and mark and measure the O*sZ* 'coordinate on the graph paper.

2. Place a horizontal laser line through the center of the same Allen screw.

3. Measure the height of the horizontal laser line above the platform with a scale to obtain O*sY′* coordinate.

G. Frontal Plane Measurement of the Global Coordinates of the Socket Alignment Vector V*s* ', V*sY′*, V*sZ′*.

This vector connects the socket angular alignment reference frame origin, O*s*', with the proximal center of socket, V*s*'. The first step will establish the proximal socket center in the frontal plane. The second step will measure the coordinates.

STEP 1
1. Mark the approximate vertical center of the notch with a wet-wipe ink pen, V*sY′*.

2. Rotate a laser line so that it passes through the center of the Allen screw that controls A-P socket angular alignment, O*s′*, and grazes the lateral side of the socket at the extreme of the fibula head relief.
3. Measure the angle of this line projected on the Y'Z' plane, γ*Vsl*.

4. Rotate a laser line so that it passes through the center of the Allen screw that controls A-P socket angular alignment, O*s*, and grazes the medial side of the socket at the extreme of the medial condyle relief.

5. Measure the angle of this line projected on the YZ plane, γ*Vsm.*

6. Calculate the bisector of the angles formed by 3. and 5. [(γ*Vsl* + γ*Vsm*)/2 = γ*VsY′Z′*].

7. Rotate a laser line to reproduce this angle and position the tripod so that the line passes through the center of the Allen screw that controls A-P socket angular alignment, O*s′*.

8.Place tape on the socket along this line. This will assist with visualization of the socket angular alignment.

9. Mark the intersection of this line with the vertical center of the notch, V*sY*', V*sZ*'.

STEP 2
10. Place a vertical laser line through the intersection (g.) and mark and measure the V*sZ* 'coordinate on graph paper.

11. Place a horizontal laser line through the intersection (g.) and measure the height of the line above the platform with a scale to obtain V*sY′*.

H. Frontal Plane Measurement of Global Orientation of the Residual Limb Vector, V*rl′*.

The residual limb vector indicates the orientation of the tibia, which may be different from the orientation of the socket. It will be represented as a unit vector, *vrl*'. Its origin can be placed where-ever desired, but the most logical origins are either the socket angular alignment reference frame origin, O*s*', or the end of the socket alignment vector, V*s*'.

1. Place tape along what appears to be the crest of the tibia, trying to keep the line as straight as possible in the frontal plane.

2. Rotate a laser line so that it touches the line in as many points as possible and measure the angle of this line projected on the Y'Z' plane, $\gamma rlY'Z'$.

I. Sagittal Plane Measurement of Foot/Distal Pylon Reference Frame Origin Global Coordinates, O*fX*' and O*dX*'.

1. Place a vertical laser line through the center of the distal pylon and mark and measure the O*fX*' (O*dX*') coordinate on the graph paper.

J. Sagittal Plane Measurement of Proximal Pylon Reference Frame Origin Global Coordinates, O*pX*'.

1. Assume O*pX'* = O*fX'* if the pylon is vertical; if in doubt, measure as in F.1 above.

K. Sagittal Plane Measurement of Socket Angular Alignment Reference Frame Origin Global Coordinate O*sX'*.

1. Place a vertical laser line through the center of the Allen screw that controls M-L angular alignment of the socket and mark and measure the O*sX* 'coordinate on graph paper.

L. Sagittal Plane Measurement of the Global Coordinates of the Socket Alignment Vector V*s* ', V*sX*'.

1. Place horizontal laser line through the approximate center of the notch (the mark in the frontal plane should give this location), or use a scale to place a horizontal laser line at distance O*sY'* above the platform.

2. Rotate a laser line so that it passes through the center of the Allen screw that controls M-L socket angular alignment, Os', and grazes the anterior side of the socket at the point of maximum notch depth, which should be a point at the same height as O*sY'*.

3. Measure the angle of this line projected on the X'Y' plane, αVsa.

4. Rotate a laser line so that it passes through the center of the Allen screw that controls M-L angular alignment, O*s*, and just grazes or is tangent to the proximal posterior profile of the socket at its narrowest point; this should be the minimum angle of clockwise laser line rotation and may be either a point on the radius of the rear shelf if it is curved concavely, or a point on the hamstrings relief, or a point on the edge of the rear brim near center if there is no shelf. No region of the socket should be visible posterior to the line at this point of tangency.

5. Measure the angle of this line projected on the X'Y' plane, αVsp.

6. Calculate the bisector of the angle formed by 3. and 5. [($\alpha Vsa + \alpha Vsp$)/2 = $\alpha VsX'Y'$].

7. Rotate a laser line to reproduce this angle and position the tripod so that the line passes through the center of the Allen screw that controls M-L socket angular alignment. Place tape on the socket along this line to help visual socket angular orientation.

8. Mark the intersection of this line with a horizontal line at height OsY'.

9. Place a vertical laser line through the intersection g. and mark and measure the VsX' coordinate on the graph paper.

M. Sagittal Plane Measurement of Global Orientation of the Residual Limb Vector, V*rl'*.

1. Place a tape along what appears to be the crest of the tibia, trying to keep the line as straight as possible in the sagittal plane.

2. Rotate a laser line so that it touches the line in as many points of the line as possible and measure the angle of this line projected on the X'Y' plane, $\alpha VrlX'Y'$.

Pylon Orientation With Respect to the Foot

A. Set Up

1. Position the foot with the toes under the elastic strap and the heel on a block of appropriate height to bring the top of the foot level. The socket may be detached, if necessary.

2. Insert Allen wrenches in the Allen screws that control foot plantar and dorsi flexion in the sagittal X"Y" plane and foot eversion and inversion in the frontal Y"Z" plane. The double primes mean that the axis of the foot has been rotated and all measurements taken thus far will have transformed global coordinates. The rotation takes place in the next step.

3. Orient the foot so that the axes of the wrenches used to adjust foot plantar and dorsi flexion are parallel to the XY plane the axes of the wrenches used to adjust foot inversion and eversion are parallel to the Z"Y" plane.

4. Check the mark placed on the foot in B.5. to verify orientation.

B. Frontal Plane Measurements of Foot/Distal Pylon Reference Frame Origin Global Coordinates O*fY''*, O*fZ''*

1. Place a vertical laser line through center of Allen screw used for foot plantar and dorsiflexion alignment and mark and measure the OfZ'' coordinate on the graph paper.

2. Place a horizontal laser line through the center of the ankle Allen screw and use a scale to measure O*fY''*.

C. Frontal Plane Measurement of Proximal Pylon Reference Frame Origin Global Coordinates O*pY''*, O*pZ''*.

These coordinates will be used for measuring pylon lean.

1. Place a vertical laser line through center of the Allen screws at the top of the pylon, or through the center of the proximal end of the pylon tube clamp if there are no screws, and mark and measure O*pZ''* on the graph paper.

2. Place a horizontal laser line through the center of the Allen screw at top of pylon or through proximal end of pylon tube clamp if there are no Allen screws.

3. Measure the height of the horizontal laser line above the platform with a scale to obtain O*pY''*.

D. Sagittal Plane Measurement of Foot/Distal Pylon Reference Frame Origin Global Coordinates, O*fX''*.

1. Place a vertical laser line through the center of the distal pylon Allen scew used for foot inversion and eversion alignment and mark and measure the O*fX* "coordinate on the graph paper.

E. Sagittal Plane Measurement of Proximal Pylon Reference Frame Origin Global Coordinates, O*pX''*.

1. Place a vertical laser line through the center of the Allen screw at the top of the pylon or through the proximal end of the pylon tube clamp if there are no Allen screws, and mark and measure O*pX''* on the graph paper.

Computations

The equations for computing foot translation and socket angular alignment follow. The end results are X'"Z'" plane coordinates for socket position relative to the center of the foot reference frame origin when the bottom of the forefoot is flat on the floor and the popliteal region of the socket is parallel to the global Z'" axis. With these coordinates the foot offset relative to the socket can be computed. The direction cosines for the socket alignment vector, V*s*, and the residual limb vector, V*rl*, also can be computed. Additional characteristics of the alignment can be computed, if necessary. Angular rotations in the X'Z' and X"Z "plane occur around the Y' and Y" axis, respectively, and are denoted by β. Angular rotations in the X"Y" plane occur about the Z' axis and are denoted by α; angular rotations in the Y"Z" plane occur around the X" axis and are denoted by γ.

The procedure computes the unit vectors for the socket alignment vector, V*s*', and the residual limb vector, V*rl*' based on measurements taken in Step 1. Coordinates of the points measured in

Step 1, above, are then adjusted for the internal-external rotation of the foot, $\beta fX'Z'$. The correction to the coordinates is carried out using a rotation matrix, |R*fr*|, which is applied to all data points (vectors) obtained in Step 1. Following this, the effects of possible pylon lean are taken into account. A rotation matrix to correct coordinates for pylon lean, |R*pl*|, is computed. This is applied to all the previously corrected vectors to bring the orientation of all vectors into the coordinate system of the second global reference frame X"Y"Z". A third correction accounts for possible rotation of the socket with respect to the adaptor, $\beta sX'Z'$, which might occur during fabrication. The latter would be manifested by a popliteal region that is not parallel to the Y'Z' plane when the axes of the socket alignment reference frame, O*s*', are parallel to the Y'Z' plane in Step 1. A rotation matrix |R*sr*| based on $\beta sX'Z'$, measured in Step 1, is used to transform the coordinates. The corrected vectors are used to compute foot translation and the socket and residual limb vectors.

A. Compute the Unit Vectors for V*s*' and V*rl*'.

1. The projection angles α and γ for vector V*s*' were determined in steps G and L, and for vector V*rl*' in steps H and M. What remains is to calculate β, the projection angles in the X'Z' plane for these vectors. The equations for this are (subscripts are omitted for clarity)

$$\tan\beta = 1/(\tan\alpha * \tan\gamma)$$
$$\beta = \arctan\beta$$

2. The unit vector direction cosines can be calculated by

$$y' = ej' = 1/\left[(\tan\beta * \tan\gamma)^2 + (\tan\gamma)^2 + 1\right]^{1/2}$$
$$x' = ei' = y * \tan\beta * \tan\gamma$$
$$z' = ek' = y * \tan\gamma$$

3. The length of socket alignment vector, which is a scalar, can be computed as

$$Vx' = VX' - OaX'$$
$$Vy' = VY' - OaY'$$
$$Vz' = VZ' - OaZ'$$

$$V_s L = \left[(Vx')^2 + (Vy')^2 + (Vz')^2\right]^{1/2}$$

The socket alignment vector can be represented by

$$V_s' = VsL * [x' + y' + z'] = VsL * [e_s']$$

4. The unit vector for Vrl' can be computed by following steps 1 and 2. Its length is 1.0.

B. Determine the Foot Rotation Correction Angle

Up to this point, measurements used in the calculations were taken with the pylon vertical. Pylon lean when the foot is flat on the floor will have an effect on calculations of the anterior-posterior and medial-lateral translation of the foot. Translations computed for a vertical pylon will change if the pylon actually leans. To account for this, the global reference frame X'Y'Z' must be rotated relative to the foot so that the axes of the Allen screws projected onto the X'Z' plane are parallel to the X and Z axes. Then the effects of pylon lean can be accounted for, since lean will represent rotations about these axes. The correction of the X'Y'Z' coordinates can be accomplished by a rotation matrix |R*fr*| that brings the axes into alignment. The angle through which the X'Y'Z' global frame must be rotated is $\beta fX'Z'$, which was measured in B above. Note that the sign of the angle must be taken into account. If, in the global X'Y'Z' reference frame the angle $\beta fX'Z'$ is measured in a clockwise direction from the X' axis, then the rotation of the X'Y'Z' reference frame in the X'Z' plane must be in a clockwise direction from the Z' axis by an equal amount, which involves a negative sign.

C. Compute the Rotation Matrix for Foot Internal-External Rotation

Let $\beta = \beta fX'Z'$ for bevity. Then the rotation matrix that transforms coordinates in the global X'Y'Z' reference frame to a corrected foot angle global frame X"Y"Z" is

$$\left|R_{G'G''}\right| = \begin{vmatrix} \cos\beta & 0 & \sin\beta \\ 0 & 1 & 0 \\ -\sin\beta & 0 & \cos\beta \end{vmatrix}$$

D. Apply the Rotation Matrix for Foot Internal-External Rotation

Then coordinates of every vector recorded in X'Y'Z' coordinates in Step 1 can be transformed to vector coordinates in the corrected foot angle global frame X"Y"Z" as follows:

$$|V_{Gu}| = \left|R_{G'G''}\right| \bullet |V_{Gr}|$$

D. Compute the Rotation Matrix for Pylon Lean [This step may not be necessary]

Pylon lean, if present, will introduce error into computations of socket angular alignment and foot translation. Thus, if lean is present, the vectors represented by coordinates in the corrected foot angle global frame must be transformed via a second rotation matrix to their respective coordinates in a global frame in which the foot or shoe is flat on the floor. The following steps perform the necessary calculations.

1. Compute the projection angles of the pylon in the X"Y" and Y"Z" planes, α and γ, respectively, using vectors obtained in "Pylon Orientation With Respect to the Foot", O*fX*", O*fY*", O*fZ*" and O*pX*", O*pY*", O*pZ*". The angle α must be measured from the X" axis with a counter-clockwise rotation having a

positive sign, and the angle γ must be measured from the Y" axis with a counter-clockwise rotation having a positive sign.

2. Compute the direction cosines x", y", z" of the leaning pylon using the methods in Step A.1 and A.2 above.

3. Solve for the following:

$\gamma'' = \arcsin(-z'')$

$\alpha'' = \arccos(y''/\cos\gamma'')$

4. The rotation matrix is

$$|R_{G''Gp''}| = \begin{vmatrix} \sin\alpha'' & \sin\alpha''\cos\gamma'' & \sin\gamma''\sin\alpha'' \\ -\sin\alpha'' & \cos\gamma''\cos\alpha'' & \sin\gamma''\cos\alpha'' \\ 0 & -\sin\gamma'' & \cos\gamma'' \end{vmatrix}$$

E. Apply the Pylon Lean Rotation Matrix

The coordinates of the vectors in the X"Y"Z" global reference frame can be corrected for pylon lean as follows:

$$|V_{Gp''}| = |R_{G''Gp''}| \bullet |V_{G''}|$$

This correction would apply to vectors with Y" coordinates greater than the Y" coordinate of O*f*, the foot reference frame origin. The axes of the global reference frame X"Y"Z" have not been rotated.

F. Compute the Rotation Matrix for Socket Rotation With Respect to the Socket Angular Alignment Reference Frame [This step may not be necessary]

This angle will exist if errors during the technical fabrication of the socket resulted in an socket angular alignment adaptor orientation that was not truly parallel to the socket axes. If the popliteal region of the socket is not parallel to the plane of the Allen screws used for medial-lateral angular alignment of the socket, an adjustment must be made so that the foot internal-external rotation angle represents the actual rotation of the foot with respect to the socket. The foot rotation angle of interest in the measurement of alignment is the centerline of the foot (as measured by the axes of the Allen screws used for foot plantar and dorsi-flexion) with respect to a line perpendicular to the plane of the popliteal region of the socket. The medial-lateral translation of the foot with respect to the socket should be computed in a direction parallel to the plane of the popliteal region. The anterior-posterior translation of the foot with respect to the socket should be computed in a direction perpendicular to the plane of the popliteal region. The angle $\beta sX'Z'$ measured in "Socket Orientation and Translation Relative to a Vertical Pylon" is the amount of rotation that the global reference frame X"Y"Z" needs to bring it into the desired orientation X'"Y'"Z'". Again, care must be taken to determine the sign of the correction, which is measured from the Z" axis.

The rotation matrix used for this is the same as in Step C above:

$$\left|R_{Gpi'''Gpi'''}\right| = \begin{vmatrix} cos\beta & 0 & sin\beta \\ 0 & 1 & 0 \\ -sin\beta & 0 & cos\beta \end{vmatrix}$$

G. Apply the Socket Rotation Matrix.

The coordinates of the vectors in the X'''Y'''Z''' global reference frame are computed with the following equation.

$$|V_{Gsi'''}| = \left|R_{Gpi'''G'''}\right| \cdot |V_{Gpi'''}|$$

H. Compute Foot Translation and Socket Angular Orientation

The vectors $V_{Gsi'''}$ are used to compute the foot offset as the distance from the proximal center of the socket at the tip of V*s*''' to the origin of the foot reference frame O*f*'''. The angular orientation of the socket in the medial-lateral direction is computed as the projection angle of Vs''' in the Y'''Z''' plane and the angular orientation of the socket in the anterior-posterior direction is computed as the projection angle of Vs''' in the X'''Y''' plane. If the unit vector for the socket alignment vector [e_s'''] has been computed, the ratios of the coordinates on consecutive axes will be the tangents of the projection angles.

$\tan\alpha = e_{sy}''' / e_{sx}'''$ where α is the anterior-posterior lean

$\tan\gamma = e_{sz}''' / e_{sy}'''$ where γ is the medial-lateral lean

This methodology can be used to measure an initial, acceptable, or perturbed alignment, and elements of the method can be used to reproduce an alignment.

Reproduction of an Initial Alignment

Reproduction of an initial alignment is simpler and involves fewer measurements. Rotation matrices need not be computed. The pylon is set up in a vertical direction as in "Socket Orientation and Translation Relative to a Vertical Pylon", and the projection angles for the foot and socket rotation are measured, *βfX'Z'* and *βsX'Z'*. Tape is placed on the socket in the frontal and sagittal planes in a vertical direction using a vertical laser. Then the foot is oriented as in "Pylon Orientation with Respect to the Foot" and distal pylon coordinates are measured in the frontal and sagittal planes.

To recreate the alignment, the procedure is reversed. With the foot oriented as in "Pylon Orientation with Respect to the Foot", the pylon lean is re-established by changing the pylon lean with the Allen screws. Then the pylon is placed in a vertical orientation, and the foot rotation is re-established to be *βfX'Z'*. Any socket angular alignment reference frame translation, O*s*', with respect the proximal pylon, O*p*', should be

re-established. The socket rotation $\beta_{sX'Z'}$ should then be re-established. Finally, the socket angular alignment should be re-established with the use of vertical laser lines. The socket anterior-posterior angular alignment is adjusted until the tape matches the vertical laser line in the sagittal plane, and the medial-lateral angular alignment is adjusted until the tape matches the vertical laser line in the frontal plane. The socket rotation $\beta_{sX'Z'}$ is checked again, and the socket alignment procedure repeated iteratively until all angles are in agreement with the original measurements.

EXPERIMENTAL DESIGN

All laboratory sessions will involve replacing the subject's current pylon with the instrumented pylon, and subjects will be asked to wear shoes of the same design, which will be provided. Following each data collection session, the instrumented pylon will be removed and replaced with the subject's original pylon, and the original alignment will be reproduced. Statistical analyses will be carried out separately for each subject. Since the goal of the research is to evaluate the usefulness of tri-axial transducer measurements for clinical use involving individual patients, the analyses will examine data at the level of single subjects (a minimum of three subjects and a maximum of five). In the discussion that follows, the number of observations applies to a single subject. For purposes of the discussion of data analysis, it will be assumed that stance occupies approximately 60% of the gait cycle and can be divided into three phases: loading (10%), support and progression (40%), and push-off (10%) (69) . The Vicon motion capture system software (Plug-in-Gait) divides the gait cycle into 50 equal time intervals. Thus the number of time intervals (hence data points) corresponding to loading, support/progression, and propulsion are 5, 20, and 5, respectively.

The first and second laboratory data collection sessions (Sessions 1 and 2) will obtain the data necessary to examine Hypotheses 1, 2, 5, and 6. Data for Hypothesis 6 will be collected following a protocol similar to that developed by Neumann (59, 70).

Sessions 1 and 2 will be identical except for the plane in which intra-socket pressure data will be obtained, and will be carried out on separate days. Both sessions will take place in the Sports Injury Research Center at UNLV. Session 1 will measure pressure changes in the frontal plane as a function of foot placement perturbations in the anterior-posterior direction, and Session 2 will measure pressure changes in the sagittal plane as a function of foot placement perturbations in the medial-lateral direction. By breaking data collection into two sessions, the potential for mental and physical fatigue affecting the subjects will be reduced. Kinetic and kinematic data will be collected simultaneously from 1.) the force-plate mounted in the floor of the laboratory (Kistler,Inc.), 2.) the motion capture system using reflective markers attached to the subjects (Vicon, Inc.), 3.) the tri-axial transducer attached to the pylon of the prosthesis, and 4.) pressure sensors placed inside the socket (Tekscan, Inc. F-Socket). Reflective markers will be attached to the pelvis, thighs, legs, and feet using tape or gum arabic. Attachment to the skin is preferred where this is feasible (e.g. thighs and legs) in order to minimize movement artifacts, and is done routinely in this manner for gait studies. A cable will be run from the tri-axial transducer to a data capture device attached to a belt worn around the subject's waist. The pressure sensors consist of very thin flat plastic films that produce negligible pressure inside the socket. It may be necessary to use tape or adhesive to secure them to the inside of the socket. "Handles" are attached to the sensors, and these handles will be attached to either the subject's prosthesis or thigh by means of a Velcro belt. Cables will

be run from the handles to a data capture device that will be attached to a belt worn around the subject's waist. Subjective measures of maximum perceived pressures and pressure changes, uncertainty with respect to perceived pressure changes, and timing of maximum pressures during the gait cycle will be elicited from subjects using numerical scales and sets of response categories (59, 70). An 11-point Borg scale will be used to measure "on the average" maximum perceived pressure (71). Each session is expected to last between three and four hours.

For Sessions 1 and 2, after the prosthesis has been instrumented with the tri-axial transducers and pressure sensors and donned, and reflective markers have been attached to the subject, the subject will be asked to walk at a self-selected comfortable speed across the force plate 10 times to produce baseline data for the session. Subjects will be asked to report the perceived timing and magnitude of maximum pressures at the four locations in the socket where maximum pressures are expected to occur. For pressures in the frontal plane (Session 1), these locations correspond to the distal tibia, distal gastrocnemius, patella tendon, and popliteal region. In the sagittal plane (Session 2), these locations correspond to the distal and proximal lateral walls of the socket, and the distal and proximal medial walls of the socket. The alignment will then be perturbed using the Haberman Alignment Device. Following each perturbation of the alignment, subjects will be asked to walk across the forceplate once. Following each walk across the force plate, subjects will be asked to report whether they perceived maximum pressure increases or decreases at the four locations, the timing of the changes, and the resulting subjective magnitudes of the pressures. There will be four perturbations about the original alignment in each of the sagittal and frontal planes (two anterior and two posterior perturbations of the foot, and two medial and two lateral perturbations of the foot). Each perturbation and the original alignment will be set randomly a total of five times, resulting in 25 separate alignments and walks across the forceplate (5 alignment settings per plane times 5 walks per alignment setting). Following each perturbation, the alignment will be returned to its original setting to allow the subject to recall the pressures it produced. If subjects request to walk a few additional steps for each alignment perturbation to better evaluate pressure magnitudes, this will be allowed. Subjects will be blinded with respect to the direction and magnitude of the alignment perturbation. Perturbations will be 7 and 14 mm away from the original alignment, unless other factors such as the size of the subject or mechanical properties of the foot necessitate greater alignment perturbations (e.g. 10 and 20 mm), or subject sensitivity to pressure necessitates a lesser alignment (e.g. 5 and 10 mm). This range of perturbations can be encountered during the dynamic alignment of a prosthesis. Walking speed and cadence will be measured during the baseline conditions and a metronome will be used to help subjects maintain a similar cadence when walking with alignment perturbations. All subjects will be asked to wear the same design of jogging shoe to minimize any effects that shoe stiffness or heel wear could have on results. The shoes will be provided from the inventory in the biomechanics laboratory at UNLV. At the end of each session, the instrumented pylon and pressure sensors will be removed and the subject's original pylon and alignment restored. The original alignment will be captured and restored by using lasers to record key alignment coordinates and angular alignments (note: this will be done with the prosthesis doffed and in a jig, which provides the stability necessary and eliminates hazards associated with laser exposure) . A V-Tech Caliper & Outrigger System (V-Tech Systems, Corp.) is available and may be used. Prior to the beginning of data collection it will be emphasized that if, at any time, a subject wishes to sit down to rest or if the amount of pressure being produced due to an alignment perturbation is greater than the subject wishes to experience, they should report this. Subjects will be allowed to sit down at any time they wish to do so, and alignment perturbations will be decreased.

To test Hypothesis 1 there will be a minimum of 300 observations per session with which to correlate or regress tri-axial transducer measurements with force plate measurements (10 baseline trials X 30 time intervals per trial), and a maximum of 1050 observations per session (35 total trials X 30 time intervals per trial). To test Hypothesis 2, there will be 750 observations per session with which to regress or correlate tri-axial transducer measurements with alignment settings (25 perturbation trials X 30 time intervals per trial). To test Hypothesis 5, there will be a minimum of 300 baseline observations per session and 150 observations per alignment perturbation setting (1 step per trial X 5 trials per setting X 30 time intervals per trial) available for correlation or regression analysis of tri-axial transducer measurements with pressure sensor measurements, and a maximum of 1500 baseline observations and 750 observations per alignment perturbation setting (5 good steps per trial X 5 trials per setting X 30 time intervals).

To test Hypothesis 6, one Receiver-Operating Characteristic curve (ROC curve of perturbation signal versus baseline noise) will be developed for each alignment perturbation based on ten subjective uncertainty responses (59, 72). The uncertainties concern whether a perturbation has resulted in a perceivable pressure change. The measurable sensitivity of the ROC curves can be related to the magnitudes and significance of changes in tri-axial transducer forces and moments and pressure sensor measurements, making it possible to compare the perceptual sensitivities of the human subjects to changes of known magnitude in socket pressures and tri-axial transducer values. To model subjective perceptions of pressure magnitude (the 11 point scale) as a function of tri-axial transducer measurements or pressure sensor measurements, one regression equation will be developed for each of the eight socket locations. For each equation, 25 observations will be used (5 settings X 5 trials per setting).

The third laboratory data collection session (Session 3) will obtain the data necessary to test Hypotheses 3 and 4, and further explore Hypothesis 6. Data collection will take place in the Sports Injury Research Laboratory or outside at nearby locations where slopes, ramps, and steps can be found. The instrumented pylon will be used, and possibly the pressure sensors if results of data collected during Sessions 1 and 2 indicate this would be desirable to further validate the utility of the tri-axial transducer. The experiment will involve 6 activities using two different feet: the subject's original foot and a SACH foot (Solid Ankle Cushion Heel). The SACH foot was selected because it has been widely used in gait studies as a baseline condition when foot designs are being compared. It is a low-cost foot featuring a simple, basic design and was the most common type of foot in use prior to the development of energy-storing feet. The six activities include 1.) walking on a level surface at a self-selected comfortable speed, 2.) walking on a level surface 10-15% faster than a self-selected comfortable speed, 3.) walking up and down a ramp of approximately 5% (the maximum recommended by Access Board/FHWA/DOT Guidelines), 4.) walking across a slope of approximately 2-5% with the prosthetic foot in both uphill and downhill positions, 5.) ascending and descending a flight of approximately 10 - 12 steps, and 6.) walking in a circle of 10 ft diameter with the prosthetic foot on both the outside and inside of the circle. Foot type will be chosen randomly and installed, and the prosthesis aligned to meet the preferences of the subject. An attempt will be made to blind subjects to the type of alternative foot being used (a SACH foot), and to which foot has been installed; however it may not be possible to completely mask foot type. Subjects will be given 30 minutes to become accustomed to the foot and then will be asked to undertake the six activities. Each activity will be repeated 5 times (10 times to capture foot positions up slope and down slope, and on the

inside and outside of the circle) for a minimum of 7 steps of data on the prosthetic foot. Seven steps will permit the first and last steps to be discarded and result in 5 steps of useable data. After completing each activity, subjects will be asked to compare resulting pressure magnitudes inside the socket with those experienced when walking on a level surface at a self-selected comfortable speed. Using the subjective data capture instruments from Sessions 1 and 2, subjects will be asked if they experienced pressure increases, the locations, the phase during gait, and the resulting perceived magnitudes. Subjects will be encouraged to report if they wish to sit down to rest or avoid intra-socket pressures of the magnitude being experienced.

ANOVA will be used to compare the peak forces, peak moments, and force and moment impulses as measured by the tri-axial transducer between the conditions (foot type and activity type). For each foot type, activities will be compared, and for each activity, foot types will be compared. Since the performance of feet of different design may vary with the phase of gait, analyses will be conducted separately for the loading, support/progression, and propulsion phases for each activity. For each phase, there will be 2 feet X 5 trials X 5 steps per trial, so each ANOVA will have 1 and 48 degrees of freedom. This should produce a power of greater than 99% for an alpha level set at 0.05. For each phase, there will be 12 tri-axial transducer measures (3 xyz peak forces + 3 xyz peak moments + 3 xyz force impulses + 3 xyz moment impulses). Similar computations apply when comparing activities for a given foot type. Activity comparisons will involve comparing only the baseline condition, walking on a level surface at a self-selected comfortable speed, to each activity. Subjective data will be analyzed using the same methods applied for Sessions 1 and 2.

All data collection will be undertaken in the presence of Dr. Neumann, who is a certified prosthetist (ABC #2944), and all prosthetic adjustments will be carried out by him personally. He will administer the survey instruments that obtain subjective data. Only one subject will be present in the lab at a time. Dr. Neumann will monitor the physical integrity of the instrumentation to ensure that the components remain securely connected. Session 1 will take place in the Sports Injury Research Center (SIRC), and Sessions 2 and 3 will take place in the SIRC or outside nearby the SIRC where ramps, slopes, and steps can be found.

TASK 3

Task 3. To develop mathematical transformations that estimate pressures at the socket-limb interface as a function of tri-axial transducer measurements obtained from the transducer.

A problem the project faces is a lack of success in recruiting a qualified graduate student. Three different students have been actively recruited, two from mechanical engineering and one from electrical engineering. One student elected not to matriculate at UNLV, one elected to pursue work in the private sector following graduation, and one opted for an alternative offer that guaranteed two years of support. Time delays in getting the project funded and securing IRB approval have negatively impacted the project. The original budget was submitted in April of 2006 and was based on 2006 rates for tuition and stipends. These rates have since increased, and the project is losing a competitive attractiveness with respect to recruiting graduate students. Work on task 3 and subsequent tasks cannot begin until personnel have been recruited successfully for the data collection phase. The task of synchronizing data streams

from the three instruments (transducer, Tekscan F-Socket, and force plate) remains to be worked out. A procedure for processing the data so that the data can be displayed and statistical analyses can be undertaken also needs to be worked out. Subjects still need to be recruited.

TASK 4

Task 4. To evaluate the clinical and research utility of tri-axial transducer data by comparing the forces and moments associated with

a.) different activities

b.) different prosthetic feet

This task can begin once instrumentation synchronization has been completed, data processing procedures have been developed, and subjects have been recruited.

TASK 5

Task 5. To develop psychometric relationships between transducer estimates of forces and moments and subjectively perceived socket pressures.

This task can begin once instrumentation synchronization has been completed, data processing procedures have been developed, and subjects have been recruited.

TASK 6

Task 6. To field test the tri-axial transducer at a site of the Army's choosing where amputees are receiving rehabilitation care.

The time required to obtain IRB approval for task 6 may place this activity in jeopardy. It cannot be planned until data have been collected and evaluated to determine whether the force sensor is producing data that has clinical value. The IRB approval process appears to take around nine months. Allowing three months for data collection after IRB approval, and nine months for data collection and analysis to accomplish Tasks 3, 4, and 5, projected completion of Task 6 is May 2010. As discussed above, it does not appear likely that the transducer can provide information that will allow an optimal alignment to be identified. However, it may be useful for interpreting socket discomfort and foot performance for activities outside the gait lab. It also may be useful for measuring rehabilitation progress in new amputees. One of the articles included in the State-of-the-Science review reported that patients appear to gradually increase weight bearing on the prosthetic limb until they are confident that it will be comfortable. This phenomenon has not been studied, but the force sensor makes such studies feasible. Potential shortcomings of the force sensor include its weight (approximately 1.8 lbs) and its size (4 inches in diameter). Similar data could be collected using the Tekscan F-Scan which weighs much less and fits inside the shoe. The F-Scan also is compatible with J-shaped ESAR feet, whereas the tri-axial transducer is not. However, the tri-axial transducer will provide additional data on the moments and horizontal forces, which the F-Scan cannot provide.

KEY RESEARCH ACCOMPLISHMENTS

Key accomplishments to date are as follows:

- Design of the experiments
- IRB approval
- Thorough systematic literature review
- Refinement of hypotheses
- Development of a methodology for measuring and reproducing an alignment
- Procurement and set-up of tri-axial transducer for data collection
- Procurement of related instrumentation

REPORTABLE OUTCOMES

No outcomes have been reported to date. Outcomes that merit consideration for publication include are the State-of-the-Science Review and the methodology for measuring an alignment.

CONCLUSION

A systematic review of the literature on transtibial prosthesis alignment indicates that a tri-axial transducer mounted distal to the socket may not provide as much clinically useful data as originally envisioned. It may not enable a clinician to identify an "optimal" alignment. It may not be useable with energy storing and return feet that incorporate and strut in place of a pylon, which includes many of the most popular feet. However, it may be useful for research studies, particularly those that seek to examine the relationship between prosthesis alignment and intra-socket pressures. The research thus far has clarified a number of quality-of- evidence issues associated with previous research on alignment outcomes, and may make a contribution to the design of experiments in the future. The length of time required to obtain IRB approval from two separate institutions and a lack of success in recruiting a qualified graduate student have created problems for implementation of data collection.

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APPENDICES
Call for Subjects

SUBJECTS NEEDED

(February 1, 2008)

UNIVERSITY OF NEVADA, LAS VEGAS PROSTHETICS STUDY

Funded by

US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

TITLE OF STUDY: Measurement of Forces and Moments Transmitted to the Residual Limb

PURPOSE OF STUDY: The purpose of the study being undertaken by the University of Nevada, Las Vegas is to evaluate a device that attaches to the pylon below the socket and measures the forces being transmitted from the pylon to the socket and limb of below-knee amputees. The goal is to determine if the device is useful for aligning prostheses, prescribing prosthetic feet and shock absorbing components, and examining the pressures created on the limb inside the socket during walking and other activities. Up to 5 subjects are needed.

PROCEDURES: Participation will involve three data collection sessions at UNLV on three separate days. Each session will last three to four hours. Prostheses will be instrumented directly below the socket and measurements taken under several experimental conditions involving different alignment settings, types of activities, and types of feet. If a cosmetic cover is used on a subject's prosthesis, it will need to be removed prior to data collection by the subject's prosthetist and reinstalled when data collection is completed. Subjects will be provided with information on the results, if desired.

ELIGIBILITY REQUIREMENTS: Subjects must

- be an active below-knee amputee age 18 years or over with a healthy residual limb having touch and pressure sensation and no open sores, and no activity limitations caused by pain;
- be able to stand or walk for periods up to 30 minutes at a time, undertake activities which could involve modest impact on the residual limb (walking up and down ramps and stairs and walking across mild slopes), and have no difficulty with balance;
- have a prosthesis with a socket that fits well; and
- have a prosthesis featuring a standard pylon with 3 ½ inches of clearance between socket and foot attachment components and a socket attachment with a standard 4-hole bolt pattern (this will be determined during an evaluation). Joint and corset designs are not eligible, and cosmetic skin coverings may be damaged during removal and reinstallation.
- Subjects must be available for data collection at UNLV between 8 am and 5 pm on weekdays.

A preliminary evaluation will be conducted at the subject's prosthetic clinic to determine eligibility.

FOR FURTHER INFORMATION, PLEASE CONTACT

EDWARD S. NEUMANN, PhD, PE, CP
CENTER FOR DISABILITY AND APPLIED BIOMECHANICS
UNIVERSITY OF NEVADA, LAS VEGAS
PHONE: 702 895 1072

email: neumann@ce.unlv.edu

Letters of Informed Consent

UNLV
UNIVERSITY OF NEVADA LAS VEGAS

INFORMED CONSENT – CANDIDATE EVALAUTION

Center for Disability and Applied Biomechanics, Department of Civil and Environmental Engineering, Department of Mechanical Engineering

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TITLE OF STUDY: Measurement of Forces and Moments Transmitted to the Residual Limb

INVESTIGATOR: Edward S. Neumann, PhD, PE, CP; PHONE NUMBER: 702 895 1072

CO-INVESTIGATOR: Woosoon Yim, PhD; PHONE NUMBER: 702 895 0956

Purpose of the Study

You have expressed interest in becoming a research subject in a study to evaluate a device called a "tri-axial transducer" that attaches directly below the socket of a prosthesis and measures the forces being transmitted from the pylon (tube) of the prosthesis to the socket and the limb. The device is 1 ½ inches high, 4 inches in diameter, and weighs 1.8 lbs. The study involves research and will be conducted on the campus of the University of Nevada, Las Vegas in or near the Sports Injury Research Center. You must meet certain requirements to be included in the study, and today we will determine if you meet those requirements. If you meet screening requirements, you will be asked to participate in three separate data collection sessions. During two of the sessions we will make minor changes in the alignment of your prosthesis, and during the third session we will change the foot and ask you walk up and down steps, ascend and descend a ramp, walk across a slope, and walk in a circle. The purpose of the study in which you have expressed interest is to evaluate the potential utility of the instrumentation to prosthetists as a means for examining the pressures experienced on the limb inside the socket, aligning prosthetic components, and prescribing prosthetic feet and shock absorbers. The study is funded by the US Army Medical Research and Materiel Command.

Participants

Altogether, three to five candidates will be asked to participate as subjects in the study. You must be available for data collection at the University of Nevada, Las Vegas between 8 am and 5 pm on weekdays.You must be age 18 or over and be an active below-knee amputee whose prosthesis meets specific requirements that allow the instrumentation to be positioned on top of the pylon just below the socket. This requires 3 ½ inches of tubing between the components that attach the tubing to the socket and foot. The components that attach the socket and foot must have a standard 4-hole bolt pattern that allows the instrumentation to be installed. Standard attachment components usually meet these bolt pattern requirements. Also, your prosthesis cannot utilize mechanical knee joints or a thigh corset. You must be able to walk at a varying cadence in the community, at speeds 10% to 15% faster than your normal walking speed; you must be able to stand or walk for 30 minutes without the need sit or rest; be able to ascend and descend steps; be able to ascend and descend ramps of 5% (an increase of 5 feet of height per 100 feet of length);

be able to walk across slopes of 2% to 5% (an increase in height of 2 to 5 feet per 100 feet of uphill length); and be able to walk in a circle with a radius of 5 feet (10 foot diameter). Your socket fit must be good, and your residual limb must be well-healed and have protective touch and deep pressure sensation. You cannot participate if you are using a preparatory prosthesis (a temporary prosthesis fit shortly after amputation surgery), have open sores on your stump or had recent surgery on it that has not healed, are experiencing pain in your stump that will be worsened by the experiments, have a loose socket fit, or have balance problems associated with the activities mentioned above. Also, your distribution of body mass cannot hide reflective markers that will be attached to you during part of the study. These criteria are necessary to minimize risk to you and to ensure that data of the type and quality needed to evaluate the instrumentation will be obtained. If you meet all the criteria, it is very likely that you will be invited to become a subject.

Procedures

The purposes of today's evaluation are twofold. First, we need to determine that your participation in laboratory data collection procedures will not expose you to any risks that might cause harm to you. Second, we need to determine that your prosthesis and residual limb meet the requirements for the study.

1.You first will be requested to complete a questionnaire that asks a series of questions about your activity levels and your ability to undertake the activities you will be requested to perform during data collection. Your answers will enable us to determine if the data collection activities may pose health risks to you or cause discomfort.

2. If, based on your answers, it appears you will be able to undertake the activities without risk or harm, and you indicate that you are willing to do so, the fit of your socket will be examined and the type of components used in your prosthesis will be determined.

3. If the socket fit is acceptable and the components meet the requirements of the study, you will be asked to take your prosthesis and suspension liner (or socks) off and your residual limb will be examined for signs of trauma, scars, grafts, or other conditions which might result in harm during data collection.

4. In order to ensure that you are able to sense pressure changes in your socket, I will test for both touch sensation and deep pressure sensation. Touch sensation will be determined by applying a series of thin monofilament fibers to six regions of your residual limb: near the end of your shin bone (tibia), the bony prominence by the head of your fibula, your calf muscle, behind and slightly below the back of your knee, the ligament just below your kneecap where your socket is notched slightly, and the bony area (condyle) at the level of your kneecap on the inside of your leg. A device called a biothesiometer, which produces vibration, may also be used. If this is used, a device which looks like an eraser will be placed at these locations and the level of vibration gradually increased until you can detect it. In order to assess deep pressure sensation, I will use my thumbs to apply light pressure on these six areas, and ask you if you can feel any pressure. I will conduct testing in a manner that prevents you from seeing your leg.

5. You will be informed immediately as to whether you meet the screening criteria for data collection. If you qualify, procedures for the data collection will be explained to you in detail. You will be given a second Letter of Informed Consent for the data collection phase, which you may take with you to study and decide if you wish to participate.

Benefits of Participation

There *may not* be direct benefits to you as a participant in this study. There will be no direct benefits from screening tests, other than the opportunity to become a subject in the study. With the study, we hope to learn how you perceive minor changes in alignment, the specific sources and magnitudes of pressure experienced in your socket, and how different types of component designs might influence these pressures. If the instrumentation is found to produce useful data, its adoption for use in prosthetics clinics may benefit amputees and prosthetists.

Risks of Participation

There are risks involved in all research studies. This study may include only minimal risks. For the screening portion, no embarrassing questions will be asked and no confidential information will be requested. The fiber sensors have rounded tips and do not cause pain. The biothesiometer does not cause pain. If the test for deep pressure sensation produces any pain, notify me immediately and I will stop applying pressure. During the examination portion, you will need to expose your residual limb, but only in the presence of trained medical personnel affiliated with your prosthetist. I have met the education, experience, and examination requirements necessary to become a certified prosthetist and am certified (ABC CP #2944). I will conduct the evaluation today.

Cost /Compensation

There *will not* be financial cost to you to participate in this evaluation today. It is estimated to take between one to two hours. *The University of Nevada, Las Vegas may not provide compensation or free medical care for an unanticipated injury sustained as a result of participating in this research study.* If your prosthesis features a cosmetic cover, it will need to be removed by your prosthetist prior to data collection at the University of Nevada, Las Vegas, and reinstalled after data collection is completed. Removal and reinstallation may result in permanent damage. This cost of this cannot be covered by the project.

Contact Information

If you have any questions or concerns about the study, you may contact Dr. Neumann at 702 895 1072**.** For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted you may contact **the UNLV Office for the Protection of Research Subjects at 702-895-2794.**

Voluntary Participation

Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with the university or your prosthetist. Your decision to either participate or to decline to participate will have no influence on the medical care you receive from your prosthetist. You are encouraged to ask Dr. Neumann questions about this study at the beginning or any time during the research study.

Confidentiality

All information gathered in this study will be kept completely confidential. No reference to you will be made in written or oral materials that could link you to this study. The only information about you that may be published in scientific papers or stated in presentations at scientific meetings will be your age, sex, weight, height, the date and reason for your amputation, your level of activity, the length of your lower leg and residual limb, the condition of your residual limb including touch and pressure sensation, and the type of components used in your prosthesis. All records will be stored in a locked facility at UNLV for at least 3 years after completion of the study. After storage, the information gathered will be destroyed. If you withdraw prior to completion of data collection, all data that has been collected will be protected and disposed of in the same manner. Representatives of the United States Army Medical Research and Materiel Command are eligible to review research records.

Participant Consent:

I have read the above information and agree to participate in this study. I am at least 18 years of age. A copy of this form has been given to me.

_____ _____

Signature of Participant Date

_____

Participant Name (Please Print)

Participant Note: Please do not sign this document if the Approval Stamp is missing or is expired.

INFORMED CONSENT – DATA COLLECTION

Center for Disability and Applied Biomechanics, Department of Civil and Environmental Engineering, Department of Mechanical Engineering

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TITLE OF STUDY: Measurement of Forces and Moments Transmitted to the Residual Limb

INVESTIGATOR: Edward S. Neumann, PhD, PE, CP; PHONE NUMBER: 702 895 1072

CO-INVESTIGATOR: Woosoon Yim, PhD; PHONE NUMBER: 702 895 0956

Purpose of the Study

You are invited to participate in a research study to evaluate a device called a "tri-axial transducer" that measures the forces being transmitted from the pylon of a prosthesis to the socket and your limb. The device is 1 ½ inches high, 4 inches in diameter, and weighs 1.8 lbs. The study will take place on the campus of the University of Nevada, Las Vegas in and near the Sports Injury Research Center. The purpose of the study is to determine the potential utility of the device for examining the pressures experienced on the limb inside the socket, aligning prosthetic components, and prescribing prosthetic feet and shock absorbers. The study is funded by the US Army Medical Research and Materiel Command. Your participation will facilitate the collection of data of the type and quality needed to evaluate the device.

Participants

You are one of three to five subjects being asked to participate in the study. You are available for data collection at the University of Nevada, Las Vegas between the hours of 8 am and 5 pm on weekdays. You are age 18 or over and an active below-knee amputee whose prosthesis meets specific requirements that allow the instrumentation to be positioned on top of the pylon just below the socket. You have 3 ½ inches of tubing between the components that attach the tubing to the socket and foot. The components that attach the socket and foot have a standard 4-hole bolt pattern that allows the instrumentation to be installed. Your prosthesis does not utilize mechanical knee joints or a thigh corset. You have indicated in the screening survey that you are able to walk at a varying cadence in the community, at speeds 10% to 15% faster than your normal walking speed; you are able to stand or walk for 30 minutes without the need sit or rest; able to ascend and descend steps; able to ascend and descend ramps of 5% (an increase of 5 feet of height per 100 feet of length); able to walk across slopes of 2% to 5% (an increase in height of 2 to 5 feet per 100 feet of uphill length); and able to walk in a circle with a radius of 5 feet (10 foot diameter). Your socket fit is good, and your residual limb is well-healed and has protective touch and deep pressure sensation. You are not using a preparatory prosthesis (a temporary prosthesis fit shortly after amputation surgery), you do not have open sores on your stump or had recent surgery on it that has not healed, you are not experiencing pain in your stump that will be worsened by the experiments, you do not have a loose socket fit, and you do not have balance problems associated with the activities mentioned above. Also, your distribution of body mass will not hide reflective markers that will be attached to you during part of the study.

Procedures

If you have a cosmetic cover on your prosthesis, it will need to be removed prior to the first data collection session and reinstalled following the last data collection session. You and I will need to arrange this with your prosthetist. You will be asked to participate in three separate data collection sessions on three separate days. The sessions are expected to last, respectively, 3 to 4 hours, 3 to 4 hours, and 3 hours (nine to eleven hours in total). We will attempt to schedule the sessions close together.

SESSION 1

Motion capture and force data will be collected simultaneously in the Sports Injury Research Laboratory at UNLV. You will need to wear shorts and clothing which fits snugly around your pelvis. During the first session, which will last approximately three to four hours,

1. You will be fitted with a pair of walking/running shoes that will be used during data collection. The shoes will be supplied to you prior to data collection and returned at the end of each session. The reason for using them is to reduce the influence that shoe design may have on results and to make it easier to compare results among participants.
2. The current pylon in your prosthesis will be replaced with a pylon containing the tri-axial transducer and an alignment device, and it will also be instrumented with thin force sensors on the inside of the socket. The sensors will be placed in your socket to record socket pressures at the same time forces in the pylon are being measured by the transducers. You will need to remove your prosthesis so that the pylon can be replaced and the sensors inserted.
3. Prior to inserting the sensors, they will need to be calibrated, which may involve placing them in your shoes and having you stand on them briefly prior to removing your prosthesis. Sensors will be placed on the front and back sides of your socket and will lie between the socket wall and your liner or socks when your prosthesis is worn. A light adhesive or tape may be used to secure the sensors, and will be cleaned off at the end of the experiment. Two small, rectangular "handles" will be attached to the two sensors on the front and back walls of the socket and will be strapped to your thighs or the pylon of your prosthesis. Cables will be attached to the handles and run to data recording units secured to your waist.
4. Your original alignment will be reproduced before you don your prosthesis. Another data recording device will be attached around your waist and connected to the transducer by a cable.
5. Reflective markers will be fastened to your feet, legs and pelvis by means of tape or a mild skin adhesive used in acting (Arabic gum). IF YOU DISCOVER THAT YOU ARE ALLERGIC TO THE ADHESIVE, PLEASE NOTIFY DR. NEUMANN IMMEDIATELY! If you develop redness, itching, swelling, blistering, weeping, crusting, rash, eruptions, hives, or sweating at the application site, an allergic reaction might be occurring.
6. You will be given instructions on how to walk so that good motion capture measurements and force-plate data can be obtained in the gait lab. While the motion capture and force plate data are being collected, the tri-axial transducer will also be collecting data on the forces occurring in the pylon of your prosthesis.
7. You first will be asked to walk across the force-plate at a self-selected comfortable pace approximately ten times. Using an 11-point scale, you will be asked to report the subjective magnitudes of the peak pressures experienced on 4 areas of your residual limb.
8. A series of experiments will be conducted during which the alignment of your pylon will be changed randomly in small increments using the alignment device. The foot will be moved forward and backward. You will not be able to see how the alignment has been changed nor will you be told how it has been changed. You will be requested to walk across the force-plate once after each setting change and asked whether the peak pressures experienced at the 4 locations inside your socket seem to have increased or decreased relative to the original alignment, how certain you are of this, and what you judge to be the subjective magnitude of the resulting pressure using the 11-point scale. The alignment will be changed a

total of 25 times, which will involve walking across the force-plate approximately 25 times for this portion of the experiment. Prior to each alignment change, your original alignment will be reproduced and you will be allowed to walk with your original alignment briefly to refresh your memory on how it feels. A metronome may be used to help you maintain the same cadence for all alignment settings. It is expected that you will experience changes in pressure at various locations on your residual limb or knee joint as alignment is varied.
9. If useable data are not obtained on a pass across the force-plate (for example, if only part of your foot contacts the force-plate instead of your entire foot), you will be asked to repeat walking across the force-plate again until useable data are obtained.
10. At the end of the session, the instrumented pylon will be replaced with your original pylon and your original alignment will be re-established. You can then don your own shoes, and are free to leave. The shoes used in the laboratory will remain in the laboratory for the next data collection session.

SESSION 2

Session 2 will be identical to Session 1 except that the thin pressure sensors will be placed on the insides of the left and right sides of your socket, and alignment changes will involve moving the foot to the left and right of its original position by small amounts. Again, you will be asked to walk at a self-selected comfortable speed across the force plate 10 times. Following this, 25 alignment changes will be made, and you will be asked to walk across the force plate once for each change and report perceived pressure changes in your socket. Prior to each alignment change, your original alignment will be reproduced to help you make a comparison.

SESSION 3

During the third session, which will last approximately three hours, you will walk on both your original foot and an alternative foot of a different design. It will take place in the Sports Injury Research Laboratory or in the vicinity of the laboratory building. You will need to wear shorts, but markers will not be attached to you.
1.You will be asked to remove your prosthesis.
2. Your pylon will again be replaced with the instrumented pylon and your original foot will be taken off and replaced with either your original foot or a different foot. You will not be told which type of foot is being used and we will attempt to conceal this, though you may be able to tell by how it feels when you walk. The shoes used during the first and second sessions will be used again.
3. You will be asked to don your prosthesis, and the recording device for the transducer will be fastened around your waist.
4. The most comfortable alignment will be produced.
5. You will be given thirty minutes to stand, sit, or walk around and become accustomed to the foot. 6. You will then be asked to perform six activities, and data on the forces occurring in the pylon will be recorded. You will be asked to perform these activities five times, taking approximately seven steps each time. The six activities are described below (A through E).

A. You will be asked to walk at a self-selected comfortable speed on level ground. After this first activity you will be asked to indicate the magnitudes of the pressures experienced in your socket at the same 8 locations used in Sessions 1 and 2 (4 associated with pressures on the front and back of your limb and 4 associated with pressures on the left and right sides), as well as the time(s) during stance when the peak seems to occur. After each of the subsequent 5 activities you will be asked to compare the maximum pressures felt in your socket to those experienced when walking on level ground at a self-selected comfortable speed, and to identify locations where the pressure has increased. For these locations you will be asked to indicate the pressures using the same 11 point scale from Sessions 1 and 2.

B. You will be asked to walk approximately 10%-15% faster than the comfortable speed and compare the maximum pressures to those in activity A (A metronome will be used to help you establish a cadence that is 10% - 15% faster than your normal comfortable speed, and also to help you maintain similar cadences throughout the experiment).

C. You will be asked to walk up and down a 5% ramp and compare the maximum pressures to those in activity A.

D. You will be asked to walk across a 2%-5% slope and compare the maximum pressures to those in activity A.

E. You will be asked to climb up and down steps and compare the maximum pressures to those in activity A.

F. You will be asked to walk in a circle with a radius of 5 feet (a 5% ramp rises approximately 5 feet in elevation per 100 feet of length, and is commonly found in cities) and compare the maximum pressures to those in activity A.

7. After completing the last activity, you will be asked to remove your prosthesis and the second foot will be attached.

8. The most comfortable alignment will be produced.

9. You will again be allowed to stand, sit, or walk around for thirty minutes to become accustomed to the foot.

10.You will be asked to repeat the same six activities five times each, and the same procedures will be followed. You will be asked to report pressures while walking at a self-selected comfortable speed on level ground and then to report pressure increases experienced during the other five activities.

11. At the end of the session, the instrumented pylon will be replaced with your original pylon, your original foot will be attached, and your original alignment will be re-established. You can then don your own shoes, and are free to leave.

Benefits of Participation

There is no direct benefit to as a participant in this study. There may be a direct benefit if you find an alignment setting that is more comfortable than your original alignment, or if you find the experimental foot preferable, but the likelihood of this is small. We hope to learn how you perceive minor changes in alignment, the specific sources and magnitudes of pressure experienced in your socket, and how different types of component designs might influence these pressures. We will provide your data to you if you wish to have it. If the instrumentation is found to produce useful data, its adoption for use in prosthetics clinics may benefit amputees and prosthetists in general.

Risks of Participation

There are risks involved in all research studies. This study may include only minimal risks. Up to a moderate amount of increased pressure may be felt on your residual limb or at your knee after some of the alignment perturbations, when performing specific activities, or when using a different type of foot. IF, AT ANY TIME DURING THE EXPERIMENT, YOU FEEL AN UNCOMFORTABLE AMOUNT OF PRESSURE AND WISH TO AVOID WALKING BECAUSE OF THIS, PLEASE NOTIFY DR. NEUMANN, WHO WILL BE SUPERVISING DATA COLLECTION. YOU SHOULD NOT WALK IF YOU FEEL IT MAY INJURE YOUR LEG OR CAUSE A LEVEL OF DISCOMFORT YOU WOULD PREFER TO AVOID. The verbal reports being requested on perceived pressure magnitude and magnitude change will require mental concentration, and may seem repetitious. The shoes provided by the laboratory may feel different from your usual shoes and require some adaptation. You may feel some physical fatigue. The recording devices and connecting cables for the sensors may feel bulky. The risk of falling is about the same as walking with the aid of a prosthesis during your daily activities. The laboratory experiments will involve walking with the cover of your prosthesis removed and your socket and suspension system exposed to other individuals working in the laboratory. If activities take place

outside of the laboratory building, others in the area not associated with the laboratory may see you walking. *Risk of damage to your prosthetic cover exists due to the need to remove and reinstall it.* This is about the same level of risk that would occur if the cover needs to be removed by your prosthetist for maintenance activities, adjustments, or to replace the foot. Project funding will not cover the cost of repairing your cosmetic cover or replacing it with a new one. None of the other components of your prosthesis (socket, foot, pylon, shock absorber) will be altered.

Cost /Compensation

There *will not* be financial cost to you to participate in this study. Any costs of parking will be covered by the project. The study will take 3 or 4 hours of your time per session, and there will be three sessions. You *will not* be given money compensation for your time. If you need to take time off from work to participate, you will not be compensated for this. If your cosmetic cover is damaged, the University of Nevada, Las Vegas, will not cover the cost of repair or replacement. *The University of Nevada, Las Vegas may not provide compensation or free medical care for an unanticipated injury sustained as a result of participating in this research study.*

Contact Information

If you have any questions or concerns about the study, you may contact Dr. Neumann at 702 895 1072**.** For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted you may contact **the UNLV Office for the Protection of Research Subjects at 702-895-2794.**

Voluntary Participation

Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with the university or your prosthetist. Refusal to participate will have no influence on the medical care you receive from your prosthetist. You are encouraged to ask Dr. Neumann questions about this study at the beginning or any time during the research study.

Confidentiality

All information gathered in this study will be kept completely confidential. No reference to you will be made in written or oral materials that could link you to this study. The only information about you that may be published in scientific papers or stated in presentations at scientific meetings will be your age, sex, weight, height, the date and reason for your amputation, your level of activity, the length of your lower leg and residual limb, the condition of your residual limb including touch and pressure sensation, the type of components used in your prosthesis, and the results of data analysis. All records will be stored in a locked facility at UNLV for at least 3 years after completion of the study. After storage, the information gathered will be destroyed. If you withdraw prior to completion of data collection, all data that has been collected will be protected and disposed of in the same manner. Representatives of the United States Army Medical Research and Materiel Command are eligible to review research records.

Participant Consent:

I have read the above information and agree to participate in this study. I am at least 18 years of age. A copy of this form has been given to me.

_____ _____

Signature of Participant Date

_____

Participant Name (Please Print)

Participant Note: Please do not sign this document if the Approval Stamp is missing or is expired.

Data Collection Forms

Code: _____ Date: _____

Session 1 & 2: Alignment Variation Subjective Assessment – AP

			Distal tibia	Gastrocnemius	Patella tendon	Popliteal
	Original peak pressure	Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag C				
Trial	Setting	Change				
1.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
2.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
3.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
4.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
5.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
6.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
7.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7

		Mag C				

Code: _____ Date: _____

Trial	Setting	Change				
8.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
9.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
10.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
11.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
12.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
13.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
14.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				

Code: _____ Date: _____

Trial	Setting	Change				
15.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
16.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
17.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
18.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
19.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
20.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
21.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				

Code: _____ Date: _____

Trial	Setting	Change				
22.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
23.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
24.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
25.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
26.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
27.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
28.	AP -2 -1 0 +1 +2		Distal tibia	Gastrocnemius	Patella tendon	Popliteal
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				

Code: _____ Date: _____

Session 1 & 2: Alignment Variation Subjective Assessment – ML

			Lateral distal	Medial distal	Lateral prox	Medial prox
	Original peak pressure	Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag C				
Trial	Setting	Change				
1.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
2.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
3.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
4.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
5.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
6.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
7.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7

		Mag C				

Code: _____ Date: _____

Trial	Setting	Change				
8.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
9.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
10.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
11.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
12.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
13.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
14.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				

Code: _____ Date: _____

15.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
16.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
17.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
18.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
19.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
20.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
21.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				

Code: _____ Date: _____

22.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
23.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
24.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
25.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
26.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
27.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				
28.	ML -2 -1 0 +1 +2		Lateral distal	Medial distal	Lateral prox	Medial prox
		Phase A	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Δpress B	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7	1 2 3 4 5 6 7
		Mag C				

Code: _____ Date: _____ Session 3: Foot and Activity Comparison
Foot type: _____

Trial										
1.	Walking @ SSCS	Region	Dist tib	Gastroc	Pat tend	Popliteal	Lat dist	Med dist	Lat prox	Med prox
		Phase	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag								
2.	Walking @ 10%-15%	Region	Dist tib	Gastroc	Pat tend	Popliteal	Lat dist	Med dist	Lat prox	Med prox
		Phase	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag								

3.	Up Ramp	Region	Dist tib	Gastroc	Pat tend	Popliteal	Lat dist	Med dist	Lat prox	Med prox
		Phase	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag								
	Down Ramp	Region	Dist tib	Gastroc	Pat tend	Popliteal	Lat dist	Med dist	Lat prox	Med prox
		Phase	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag								
4.	Across slope	Region	Dist tib	Gastroc	Pat tend	Popliteal	Lat dist	Med dist	Lat prox	Med prox
	Prosthetic uphill	Phase	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag								
	Across slope	Region	Dist tib	Gastroc	Pat tend	Popliteal	Lat dist	Med dist	Lat prox	Med prox
	Prosthetic downhill	Phase	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag								

5	Steps - up	Region	Dist tib	Gastroc	Pat tend	Popliteal	Lat dist	Med dist	Lat prox	Med prox
		Phase	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag								
	Steps - down	Region	Dist tib	Gastroc	Pat tend	Popliteal	Lat dist	Med dist	Lat prox	Med prox
		Phase	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag								
6	Circle	Region	Dist tib	Gastroc	Pat tend	Popliteal	Lat dist	Med dist	Lat prox	Med prox
	Prosthetic inside	Phase	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag								
	Circle	Region	Dist tib	Gastroc	Pat tend	Popliteal	Lat dist	Med dist	Lat prox	Med prox
	Prosthetic outside	Phase	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
		Mag								

Sessions 1 and 2

We want you to compare the ORIGINAL alignment that you have when we begin today's experiment to several MODIFIED alignments. Several locations in your socket will be pointed out to you. We will produce the ORIGINAL alignment and ask you to walk across the force plate. For each location that we point out, try to identify and remember what the <u>maximum</u> pressure feels like for the ORIGINAL alignment, <u>on the average over a series of steps</u>. Also try to identify and remember when this maximum pressure occurs –do you notice it mostly in early stance when your weight is mainly on the heel of your prosthetic foot, mostly in later stance when your weight is mainly on the toes, about equally during both of these periods, or do you notice it mostly in-between these two periods when your foot is flat on the ground? We will ask a series of questions concerning how the maximum pressures of this ORIGINAL alignment feel to you and when you notice them.

We will then modify your alignment, have you walk across the force plate again, and ask you a series of questions so that we can compare how the MODIFIED alignment feels compared to the ORIGINAL alignment.

We then will ask you about the acceptability of this alignment.

Sessions 1 and 2

Question A: For the location specified, at what point in time do you feel the greatest pressure on the average as you walk? Please select one of the following:

1. Nearer the beginning of stance, when most of my weight is mainly on the heel of my prosthetic foot

2. Nearer the end of stance, when most of my weight is mainly on the toes of my prosthetic foot

3. About equally at both the beginning and the end

4. In between when my foot is flat on the ground

5. It varies or is hard to tell

Sessions 1 and 2

Question B: How does the <u>greatest</u> pressure <u>on the average</u> of this MODIFIED alignment feel in comparison to the ORIGINAL alignment?

Use statements 1 through 3 if it feels like the pressure produced by the MODIFIED alignment might be GREATER. Use statements 5 through 7 if it feels like the pressure produced by the MODIFIED alignment might be LESS. Use statement 4 if you are <u>sure</u> the pressure produced by the MODIFIED and ORIGINAL alignment feels the SAME.

With the MODIFIED alignment, <u>on the average</u>, I am

1. SURE the pressure feels GREATER
2. FAIRLY SURE the pressure feels GREATER
3. NOT SURE, but the pressure feels like it may be GREATER

4. SURE the pressure feels the SAME

5. NOT SURE but the pressure feels like it may be LESS
6. FAIRLY SURE the pressure feels LESS
7. SURE the pressure feels LESS

Sessions 1, 2, 3

Question C: Please select a number between 0 and 11 that matches the amount of PRESSURE you are experiencing at the location specified. It may be easiest to start with a verbal expression and then choose a number.

0	**Nothing at all**	**“No Pressure”**
0.3		
0.5	**Extremely weak**	**Just noticeable**
1	**Very weak**	
1.5		
2	**Weak**	**Light**
2.5		
3	**Moderate**	
4		
5	**Strong**	**Heavy**
6		
7	**Very strong**	
8		
9		
10	**Extremely strong (almost the maximum)**	
11		

*** The maximum I can tolerate**

Question D: Does this alignment feel comfortable or acceptable?

1. **Yes**

2. **No**

Question E: How certain are you of this?

1. **Very Certain**

2. **Somewhat Certain**

3. **Somewhat Uncertain**

4. **Very Uncertain**